NATIONAL QUALITY FORUM
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Memo

September 22, 2020

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 September 22, 2020 from 3:00-5:00pm 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 measures under consideration and
- Determine whether reconsideration of any measures or other courses of action are warranted.

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 (see comment table and additional documents included with the call materials).
3. Review the NQF members' expressions of support of the submitted measures.
4. Be prepared to provide feedback and input on proposed post-evaluation comment responses.

Conference Call Information

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

1. **Speaker dial-in #:** **800-768-2983** / Access code: **2770682**
2. **Web link:** https://core.callinfo.com/callme/?ap=8007682983&ac=2770682&role=p&mode=ad

Background

Medical errors and adverse events are major threats to patient safety in healthcare and are linked to >100,000 preventable deaths per year in the United States. Patient-safety related events occur across all settings including hospitals and outpatient clinics, as well as nursing homes, rehabilitation facilities, and others. Patient-safety related events include a variety of preventable outcomes, including healthcare-associated infections, falls, pressure ulcers.

The National Quality Forum's (NQF) portfolio of safety measures spans a variety of topical areas and includes such outcomes, as well as important, measurable processes in healthcare that are associated

with patient safety. Public accountability and quality improvement programs use many measures from the NQF portfolio. Nevertheless, significant gaps in patient safety persist. Over more than a decade, NQF's portfolio has expanded to address current and evolving public health issues such as the opioid crisis. As electronic health records have become increasingly prevalent in healthcare, it is important to develop measures that monitor and improve safety events that may be caused by the technology itself.

The Patient Safety Standing Committee is the group that oversees the NQF patient safety measure portfolio. The Committee evaluates newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifies portfolio gaps, provides feedback on gaps in measurement, and conducts ad hoc reviews. On June 18th and 19th, 2020, the Patient Safety Standing Committee evaluated two measures against NQF's standard evaluation criteria.

Critical issues discussed during the meeting included the importance of measures that are integrated into the design of electronic health records (EHRs) and that measures should be feasibly adopted without barriers such as high licensing fees.

For this cycle, the Standing Committee evaluated one newly submitted measure and one measure undergoing maintenance review against NQF's standard evaluation criteria. The Standing Committee recommended both measures for endorsement. The measures are:

- 3558 Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance)
- 2723 Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure (New York-Presbyterian Hospital)

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 pre-evaluation comment period was open from April 24-June 5, 2020 for the measures under review. The comments received were for Measure 3558, Initial Opioid Prescribing for Long Duration (IOP-LD) with concerns about adequate evidence, unintended negative consequences, and the definition of "opioid naive". All of these pre-evaluation comments were provided to the Committee prior to the measure evaluation meeting.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on July 27, 2020 for 30 calendar days. During this commenting period, NQF received five comments from four member organizations and four comments were received from the public:

Member Council	# of Member Organizations Who Commented
Health Plan	1

Member Council	# of Member Organizations Who Commented
Health Professional	3

We have included all comments that we received (both pre- and post-evaluation) in the comment table (excel spreadsheet) posted to the Committee SharePoint site. This comment table contains the commenter's name, comment, associated measure, topic (if applicable), and—for the post-evaluation comments—draft responses (including measure steward/developer responses) for the Committee's consideration. Please review this table in advance of the meeting and consider the individual comments received and the proposed responses to each.

Comments and Their Disposition

Measure-Specific Comments

Please note that the following comments are abbreviated for the purposes of this memo. For full comment text, please refer to the Patient Safety Spring 2020 Comment Table.

Measure 3558: Initial Opioid Prescribing for Long Duration (IOP-LD)

The American Geriatrics Society (AGS) has concerns about the appropriateness of this measure for older adults and for the clinicians who see a preponderance of older adults. Broadly speaking, long-term opioid dependence is less of a concern among this population, particularly those nearing the end of life. The decision to exclude patients in hospice or with a cancer diagnosis is a good acknowledgment of instances where an opioid prescription is likely to be appropriate, but there are likely additional exclusions that could be made to ensure geriatricians aren't penalized for addressing chronic or acute pain among patients who are not at risk for long term addiction. Additionally, we would like to see more evidence on why >7 day supply was chosen. The measure seems to imply that prescribing more than a 7-day supply when initiating opioids is inappropriate, but we did not see any evidence supporting this being the case. The measure also doesn't seem to consider if the patient had recent procedures such as surgery or other injuries that may justify the opioid use.

Measure Steward/Developer Response:

PQA appreciates the AGS' feedback on the IOP-LD measure. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts. As additional exclusions are identified to be potentially appropriate, they will be considered through this robust process.

The 7-day threshold was chosen based recommendations in the 2016 CDC Guidelines for Prescribing Opioids for Chronic Pain, noting that "When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed [Recommendation category A, evidence type 4]. This recommendation has been supported by a significant body of research that has emerged since the guideline was released, with strong empirical evidence regarding the extent to which additional days' supply increases risk of long-term opioid use, especially the work by Shah in the CDC MMR weekly reports (1), Brat (2), Zhang (3), among others. For more information, we recommend referring to the measure's evidence attachment.

Finally, we note that literature such as Zhang et al demonstrate that the risks associated with an initial prescription days' supply exceeding 7-days was present in a Medicare Advantage population, demonstrating that even older Americans face risks associated with initial opioid prescribing at long duration; furthermore, Brat et al demonstrated that these risks are also present in post-surgical patients.

1)Shah A, Hayes CJ, Martin BC. Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use — United States, 2006–2015. MMWR Morb Mortal Wkly Rep 2017;66:265–269. DOI: http://dx.doi.org/10.15585/mmwr.mm6610a1external icon.

2)Brat GA, Agniel D, Beam A, et al. Postsurgical prescriptions for opioid naive patients and association with overdose and misuse: retrospective cohort study. BMJ. 2018;360:j5790. Published 2018 Jan 17. doi:10.1136/bmj.j5790

3) Zhang Y, Johnson P, Jeng PJ, et al. First Opioid Prescription and Subsequent High-Risk Opioid Use: a National Study of Privately Insured and Medicare Advantage Adults. J Gen Intern Med. 2018;33(12):2156-2162. doi:10.1007/s11606-018-4628-y

Proposed Committee Response:

Thank you for your comment. The Committee previously reviewed the evidence for this measure and agreed that the evidence provided supports the measure. The Committee also recommends to the developer that as additional exclusions are identified and are appropriate, they consider them in future updates of this measure.

Action Item:

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

While Magellan Health supports the measure, the note included in the proposed denominator of the algorithm, "[i]f multiple prescriptions for opioids are dispensed on the same day, calculate the number of days covered by an opioid using the prescription claim with the longest days' supply," misses an opportunity to address one area of potential abuse. For example, where multiple prescriptions are written on the same day, the measure uses the longest. So, for instance, where three providers each

prescribe three days' worth of opioids, the possibility exists of having a greater number of pills that could be used beyond seven days. While we recognize that adjudication systems may reject a prescription where one was filled the same day, the measure should be additive to avoid possibility of misuse. The IOP-LD measure fills a recognized need in opioid measurement and seeks to identify opportunities to reduce conversion to chronic opioid use and misuse before it occurs. Likewise, the IOP-LD measure identifies opportunities for early intervention, unlike other opioid measures that are more retrospective in nature. It is a feasible, actionable, and evidence-based measure that can improve patient safety.

Measure Steward/Developer Response:

PQA appreciates Magellan's support and feedback on the IOP-LD measure regarding interpretation of multiple opioid claims that occur on the same day. The IOP-LD measure's methodology in this case is aligned with other PQA opioid measures and accounts for the fact that multiple opioids may be prescribed to be taken concurrently. In such cases, adding days' supply of multiple opioid claims received on the same day may overestimate the true days' supply. However, the PQA team will take this under advisement for future consideration. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multistakeholder panels composed of clinical and measurement science experts.

Proposed Committee Response:

Thank you for your comment. The Committee previously reviewed the measure specifications and agreed with the developer's approach. However, the Committee recommends that the developer monitor for any unintended consequences and update the measure accordingly.

Action Item:

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

The American Society of Consultant Pharmacists (ASCP) cautions PQA and National Quality Forum (NQF) of the issues that this quality measure could pose to patients and clinicians in long-term care (LTC) settings. We agree that patients with cancer, sickle cell disease, or those who were in hospice at any point during the measurement year or the 90 days prior to the first day of the measurement year should be excluded to accurately capture the number of patients who were inappropriately prescribed more than a 7-days' supply of opioids. However, we believe that long-term care (LTC) settings should also be excluded from this measure because of the mitigation strategies in place to ensure accurate and safe prescribing of opioid medications and the type of admissions facilities commonly see today. Patients are frequently admitted to facilities for post-acute care following surgery or for therapy and rehabilitation. In many cases, an opioid-naïve patient may require acute pain management for slightly more extended time periods. Due to this robust framework of opioid management that exists in LTC settings, we ask that NQF adopt an exclusion for long-term care to help ensure patient access to pain management in these settings and not duplicate burdensome administrative systems.

Measure Steward/Developer Response:

PQA appreciates ASCP's support and feedback on the IOP-LD measure regarding a potential exclusion for individuals in long-term care. PQA considers changes to PQA-endorsed measures through a standardized, transparent, consensus-based process involving several multi-stakeholder panels composed of clinical and measurement science experts. The PQA team is currently evaluating the appropriateness and feasibility of adding an exclusion for individuals in long-term care and will consider this potential change through our standardized and robust maintenance process.

Proposed Committee Response:

Thank you for your comment. The Committee previously reviewed specifications of this measures and agreed to pass the measure. However, the Committee recommends to the developer that as additional exclusions are identified and are appropriate, they consider them in future updates of this measure.

Action Item:

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

The American Society of Health-System Pharmacists urges careful consideration of any potential impact on pain management or access to medications for opioid use disorder (OUD), namely methadone. We believe that the measure developer has constructed IOP-LD in a way that allows for a lookback period that carefully balances identification of a patient that is opioid naïve and a patient that may be experiencing a new, acute pain episode. We encourage careful evaluation of that balance as the measure is implemented. In addition, we believe the inclusion of methadone, identified through outpatient prescription claims, will accurately differentiate methadone that is indicated for pain from methadone prescribed for OUD, which is currently restricted to be dispensed from federally certified opioid treatment programs only. Of note, this is a specification that the Pharmacy Quality Alliance has used in all of their opioid measures, without any reports of unintentional access limitations to methadone for OUD. If measure implementation for IOP-LD reveals otherwise, we urge the measure developer to carefully evaluate the inclusion of methadone. We believe IOP-LD, as a retrospective population-level measure will provide valuable insight into initial opioid prescribing practices for the purpose of identifying areas of improvement while filling an important public health measure gap.

Measure Steward/Developer Response:

PQA appreciates ASHP's support of the IOP-LD measure and thoughtfulness on the inclusion of methadone. As ASHP notes, methadone identified through prescription claims can accurately differentiate methadone that is indicated used for medication-assisted treatment of opioid use disorder (OUD), which is restricted to be dispensed only from federally certified opioid treatment programs. This approach to inclusion of methadone is consistent with other PQA opioid measures implemented in several federal programs, and PQA has not received feedback or evidence of unintended consequences related to methadone inclusion in this manner. As IOP-LD is implemented, PQA will continue to monitor for feedback and will evaluate any appropriate changes through our standardized, transparent, consensus-based maintenance process.

Proposed Committee Response:

Thank you for your comment. The Committee previously reviewed specifications of this measures and agreed to pass the measure. However, the Committee recommends that the developer monitor for any unintended consequences and update the measure accordingly.

Action Item:

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

Kaiser Permanente believes the Initial Opioid Prescribing – Long Duration measure fills a recognized need in opioid measurement and seeks to uncover opportunities to reduce conversion to chronic opioid use and misuse before it occurs. Likewise, the Initial Opioid Prescribing – Long Duration measure identifies opportunities for early intervention, unlike other opioid measures that are more retrospective in nature. It is a feasible, actionable, and evidence-based measure that can improve patient safety.

Proposed Committee Response:

Thank you for your comment.

Action Item:

No Committee action required.

The University of Mississippi-Center for Pharmaceutical Marketing and Management feels strongly about the value of this measure in monitoring the quality of opioid prescribing in the United States and would strongly encourage the committee to endorse this measure. A key component of the quality of opioid prescribing is the nature of the initial opioid prescription (IOP). I believe this measure goes a long way in preventing chronic use of opioids and decreasing high-risk prescriptions. Because the measure only includes an opioid-naïve population, it also ensures that it does not impact individuals with pre-existing chronic pain who have need for opioid prescriptions with a longer duration. Finally, by quantifying only the initial prescription alone, this measure encourages better patient-provider communication and coordination to transition from an acute pain episode to a long-term episode. This can help ensure that long-term prescribing of opioids is managed in a way that is safe and appropriately monitored by a healthcare provider. Overall, the measure is well supported by scientific evidence, is feasible, and covers a critical measure gap.

Proposed Committee Response:

Thank you for your comment.

Action Item:

No Committee action required.

Humana supports the continued development of quality measures to impact opioid utilization that may lead to higher likelihood for high-risk and long-term opioid use, misuse, overdose, and other negative outcomes. We fully support the evidence that long duration of initial opioid prescriptions may lead to and increase opportunities for harm. Currently the Centers for Medicare and Medicaid Services allow for the health plan to place point of sale edits for opioid naïve members at 7 days. We would like to request clarification if patient safety edits geared to impact this measure will be required to be submitted additionally in the annual opioid management templates submitted to CMS or if there will be specific rule making that will allow for patient safety edits that are aimed at curbing this quality measure through normal patient safety processes.

Measure Steward/Developer Response:

PQA appreciates Humana's comment in support of the IOP-LD measure. Although the IOP-LD measure is included in the CMS Part D Patient Safety Reports program, the PQA team is not able to provide insight on future CMS implementations of related health plan patient safety edits and opioid management templates. PQA recommends that Humana bring this question to CMS for further clarification.

Proposed Committee Response:

Thank you for your comment. The Committee does not have oversight in the decision-making of future CMS implementations of related health plan patient safety edits and opioid management templates. The Committee recommends that the commenter bring this question to CMS for further clarification.

Action Item:

No Committee action required.

Measure 2723: Wrong-Patient Retract-and-Reorder (Wrong Patient-RAR) Measure

American Geriatrics Society believes the measure appears to have questionable face validity as it measures the occurrence of a mistake and nearly immediate correction of this mistake. We question why catching an error before any harm could be done would be a good signal for practices that could harm patient safety. More validation that the rate and retracted and replaced ordered was correlated with instances where medications are ordered for the wrong patient and not caught would be helpful in making this case. With respect to older adults, one concern is whether the rate of RARs was a function of the number of prescriptions being ordered (I.e., more prescriptions ordered equals a greater risk of making a mistake). If this is the case, it would be important not to risk adjust these measures for patient age or complexity, so that providers are held accountable for getting orders correct for more complex patients. It looks like this measure is not risk adjusted, but rather can be reported within age strata.

Measure Steward/Developer Response:

Thank you for your comments. First, we agree that correlation between near-miss errors and errors that reach the patient is of interest. Nevertheless, the use of near-miss errors to test safety improvements in healthcare is endorsed by every major organization dedicated to improving patient safety, including the Agency for Healthcare Research and Quality, Institute of Medicine, World Health Organization, Institute for Healthcare Improvement, and The Joint Commission, because near-miss errors follow the same pathway as errors that cause harm.1 Near-miss errors are invaluable in quality improvement efforts and patient safety research, as they occur up to 100 times more frequently than errors that reach the patient and thus provide a sufficient number of outcome events to test the effectiveness of safety interventions.1

Second, the RAR rate is not risk adjusted, but can be stratified by location, provider, patient, or order characteristics.

1) Aspden P, Corrigan JM, Wolcott J, Erickson SM, eds. Patient Safety: Achieving a New Standard for Care. Washington (DC): National Academies Press (US); 2004. Patient Safety: Achieving a New Standard for Care.

Proposed Committee Response:

Thank you for your comments. The Committee previously reviewed the importance and validity of this measure and passed the measure on these criteria. Additionally, this measure is not risk adjusted, but can be stratified.

Action Item:

The Committee should review the comments and the developer's response and be prepared to discuss any recommendations for the developer to consider.

Baylor Scott & White Health believe that while WPRAR is a measure than can capture some errors, wouldn't a system that captured the "reason for order cancellation" be more direct? It could also be used dynamically to find problems rather than the single focus of WPRAR. Is this the best use of our resources? If the concept is to passively report WPRAR statistics by organization, that's interesting but it's unlikely to change behavior. How is implementation of this measurement going to improve quality? The document is inconsistent in its use of "provider" and "clinician", which are not the same thing. A "provider" can be a healthcare organization, a nurse, a therapist, a physician or many other people or even things.

Measure Steward/Developer Response:

Thank you for your comments and suggestions. First, we agree about the importance of understanding the reasons for order cancellations, which we have examined in validation studies of the measure and has been done in other studies of order errors (Adelman 2013, Hickman 2017, Abraham 2018). However, as the first and only fully automated measure of order errors in electronic health record (EHR) systems, the WPRAR measure serves to quantify the rate of wrong-patient orders for accountability, surveillance, and quality improvement activities.

Second, placing orders for the wrong patient occurs frequently and has the potential to cause serious harm. We agree that there are other types of errors that are important to measure, and we are in the process of developing and validating additional measures of medication order errors. These RAR measures use SQL queries that can be readily programmed into the EHR and other electronic data systems, without conducting labor-intensive chart review or relying on voluntary reporting of errors. Automated surveillance, in which electronic information systems are used to identify errors, has the potential to be a significantly more efficient and effective approach for identifying errors.

Third, this measure has been used to evaluate the effectiveness of several different interventions aimed at improving patient identification and preventing wrong-patient orders in varied clinical settings, including in the neonatal intensive care unit. Rates have been shown to be sensitive to change in response to intervention and to vary by clinical setting (inpatient vs emergency department vs outpatient). The measure is an indicator of where improvement is needed and, importantly, provides a systematic method of measuring improvement.

Finally, we recognize the inconsistent use of “provider” and “clinician”. For future submissions, we will use the term “ordering clinician”. We thank you again for your comments and suggestions.

Proposed Committee Response:

Thank you for your comments. The Committee previously reviewed the importance and validity of this measure and passed the measure on these criteria. The Committee recommends that the developer be more consistent with the term used to describe a clinician in future updates to the measure.

Action Item:

The Committee should review the comments and the developer’s response and be prepared to discuss any recommendations for the developer to consider.

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. Two NQF member provided their expression of support (one support; one non-support). See Appendix A.

Appendix A: NQF Member Expression of Support Results

Two NQF members provided their expressions of support/nonsupport. One of two measures under consideration received support from NQF members. Results for each measure are provided below.

Measure 3558: Initial Opioid Prescribing for Long Duration (IOP-LD) (Pharmacy Quality Alliance)

Member Council	Support	Do Not Support	Total
Health Professional	1	1	2