NATIONAL QUALITY FORUM
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Memo

June 4, 2021

To: Patient Safety Standing Committee

From: National Quality Forum (NQF) staff

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

Purpose of the Call

The Patient Safety Standing Committee will meet via web meeting on June 4, 2021 from 1:00-3:00PM 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 or non-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 meeting materials).
3. Review the NQF members' expressions of support or non-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:

Meeting link: https://nqf.webex.com/nqf/j.php?MTID=m430c1bf3f057212eb24263ebde2d0457
Meeting number: 173 096 9506
Password: 6rEJ43XEPJJ
Join by video system: Dial 1730969506@nqf.webex.com
You can also dial 173.243.2.68 and enter your meeting number.
Join by phone: 1-844-621-3956 United States Toll Free
+1-415-655-0001 US Toll
Access code: 173 096 9506 Global call-in numbers | Toll-free calling restrictions

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. These events include a variety of preventable outcomes, including healthcare-associated infections, falls, pressure ulcers, etc.

The NQF portfolio of safety measures spans a variety of topical areas and includes 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 Standing 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 February 10, 2021, the Patient Safety Standing Committee evaluated six measures undergoing maintenance. The Standing Committee recommended four measures for endorsement. The measures are:

- 0468: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization
- 0531: Patient Safety Indicator (PSI) 90: Patient Safety and Adverse Events Composite
- 1893: Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization
- 2993: Potentially Harmful Drug-Disease Interactions in Older Adults (DDE)

The Standing Committee did not pass the following measure on evidence and will revote on this criterion during the June 4, 2021 Post-Comment Web Meeting:

- 0097: Medication Reconciliation Post-Discharge

The Standing Committee did not reach consensus on evidence for the following measure and will revote on this criterion during the June 4, 2021 Post-Comment Web Meeting:

- 0022: Use of High-Risk Medications in Older Adults (DAE)

Comments Received

NQF receives 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 December 15, 2020 to January 15, 2021 for the measures under review. The majority of the comments received were

in opposition to measure #0468, #0531, and #1893, indicating concern around whether the measure meets the scientific acceptability criteria. All of these pre-evaluation comments were provided to the Standing Committee for their consideration 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 March 25, 2021 for 30 calendar days. During this commenting period, NQF received ten comments from five member organizations and two comments from the public:

Member Council	# of Member Organizations Who Commented
Health Professional	3
Provider Organization	1
QMRI	1

We have included all comments that we received (both pre- and post-evaluation) in the comment table (excel spreadsheet) posted to the Standing 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 Standing Committee's consideration. Please review this table in advance of the meeting and consider the individual comments received and the proposed responses. The Standing Committee's recommendations will be reviewed by the Consensus Standards Approval Committee (CSAC) on June 29-30, 2021. The CSAC will determine whether or not to uphold the Standing Committee's recommendation for each measure submitted for endorsement consideration. All Standing Committee members are encouraged to attend the CSAC meeting to listen to the discussion.

In order to facilitate discussion, the majority of the post-evaluation comments have been categorized into major topic areas or themes. Although all comments are subject to discussion, the intent is not to discuss each individual comment on the June 4, 2021 post-comment call. Instead, we will spend the majority of the time considering the themes and the measures-specific comments discussed below. Please note that the organization of the comments into major topic areas is not an attempt to limit Standing Committee discussion. Additionally, please note measure stewards/developers were asked to respond where appropriate. Where possible, NQF staff has proposed draft responses for the Committee to consider.

Comments and Their Disposition

Themed Comments

For measures *NQF #0468 - Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization* and *NQF #1893 - Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization*, two major themes were identified in the post-evaluation comments, as follows:

1. Non-support due to concerns around reliability threshold and intraclass correlation coefficients at the minimum sample size.

2. Concern regarding the lack of inclusion of social risk factors in the risk adjustment model.

Measure Steward/Developer Response for 0468:

Reliability

In the testing attachment for this measure, we provided both split-sample and signal-to-noise reliability. Both the split-sample and signal-to noise reliability results indicate sufficient measure score reliability.

As a metric of agreement, we calculated the ICC for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSMR for each hospital was 0.668. The split-sample reliability score represents the lower bound of estimate of the true measure reliability.

We calculated the signal-to-noise reliability score for each hospital with at least 25 admissions. The median reliability score was 0.78, ranging from 0.31 to 0.98. The 25th and 75th percentiles were 0.59 and 0.88, respectively.

Social Risk Factor Adjustment

While there is a conceptual pathway by which patients with social risk factors (SRFs) could experience worse outcomes, the empiric evidence does not support risk adjustment at the hospital level.

As presented in the testing attachment of the NQF submission for this measure, our main empiric finding is that adjusting for social risk has little impact on measure scores – mean changes in measure scores are small, and correlations between measure scores calculated with and without adjustment for social risk are near 1.

In additional analyses we have shown that there is little correlation between measure scores and hospitals' proportion of patients with social risk (DE and low AHRQ SES) across all hospitals, and in the fifth quintile we see a significant negative correlation (PN), meaning that the higher the proportion of patients with social risk, the better (lower) the mortality scores of the hospital.

Given these empiric findings, ASPE's recommendation to not risk adjust publicly reported quality measures for social risk (ASPE, 2020), and complex pathways which could explain the relationship between SRFs and mortality (and do not all support risk-adjustment), CMS chose to not incorporate SRF variables in this measure.

References:

Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). Second Report to Congress: Social Risk Factors and Performance in Medicare's Value-based Purchasing Programs. 2020; https://aspe.hhs.gov/system/files/pdf/263676/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report.pdf. Accessed May 4, 2021.

Measure Steward/Developer Response for 1893:
Reliability

In the testing attachment for this measure, we provided both split-sample and signal-to-noise reliability. Both the split-sample and signal-to noise reliability results indicate sufficient measure score reliability.

As a metric of agreement, we calculated the ICC for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSMR for each hospital was 0.477. The split-sample reliability score represents the lower bound of estimate of the true measure reliability.

We also calculated the signal-to-noise reliability score for each hospital with at least 25 admissions. The median reliability score was 0.72, ranging from 0.32 to 0.97. The 25th and 75th percentiles were 0.54 and 0.83, respectively. The median reliability score demonstrates moderate reliability.

Social Risk Factor Adjustment

While there is a conceptual pathway by which patients with social risk factors (SRFs) could experience worse outcomes, the empiric evidence does not support risk adjustment at the hospital level.

As presented in the testing attachment of the NQF submission for this measure, our main empiric finding is that adjusting for social risk has little impact on measure scores – mean changes in measure scores are small, and correlations between measure scores calculated with and without adjustment for social risk are near 1.

In additional analyses we have shown that there is little correlation between measure scores and hospitals' proportion of patients with social risk (DE and low AHRQ SES) across all hospitals, and in the fifth quintile we see no significant association."

Proposed Committee Response:
The Standing Committee thanks the commenters for their comments. The Standing Committee and the NQF Scientific Methods Panel have previously considered the scientific acceptability of these measures, including the reliability testing and risk adjustment models. In evaluating these measures against NQF's endorsement criteria, the Standing Committee determined to recommend these measures for endorsement.

Action Item:
Review the comments received and determine whether to accept the proposed Standing Committee response.

Measure-Specific Comments

0022: Use of High-Risk Medications in Older Adults (DAE)

- The Use of High-Risk Medications in Older Adults (DAE) measure is based on Table 2 of the American Geriatrics Society (AGS) Beers Criteria, which includes drugs recommended to be avoided for all older adults. These criteria are used by a wide range of stakeholders including clinicians, researchers, payors, healthcare systems, and regulators with the intent of educating

clinicians and patients on potentially inappropriate medications, reducing adverse drug events, and assessing quality of care, cost and patterns of drug use in older adults (Steinman et al, 2015; AGS, 2019). The AGS Beers Criteria are updated every three to four years. For the 2019 update, AGS convened an expert panel comprised of 13 clinicians, including pharmacists, physicians and nurses with experience in a variety of practice settings. Evidence to update the Beers Criteria included new literature since the last update in 2015. The literature search focused on controlled clinical trials, observational studies, systematic reviews and meta-analyses with older adult participants for individual drugs or drug classes. Medications with low utilization were excluded from the search to focus the Beers Criteria on more commonly used drugs. The panel reviewed literature from February 2016 to May 2018 and identified over 17,000 references, of which 67 systematic reviews and meta-analyses, 29 controlled clinical trials, and 281 observational studies were selected for full-text review. These were included in the Beers Criteria evidence tables and evaluated using the GRADE guidelines and the American College of Physicians' evidence grading framework (Guyatt et al., 2011; Qaseem et al., 2010). While the Panel does not research how the overall AGS Beers Criteria is linked to outcomes, they do review the literature for each drug class individually for links to negative outcomes. For example, there are several studies, including clinical trials that suggest central nervous system drugs, such as antidepressants and barbiturates, are associated with greater risk of falls and fractures in older adults (Hanlon et al., 2017; Macri et al., 2017; Marcum et al., 2016; Naples et al., Torvinen et al., 2017; Wang et al., 2016). Similarly, the panel identified additional studies since the last update linking the use of long-acting sulfonylureas with higher risk of hypoglycemia in older adults (Douros et al., 2017; Parekh et al., 2014). The medications from Table 2 in the Beers Criteria reflected in DAE (#0022) all have strong recommendations to avoid and 15 out of 20 drug classes have strong or moderate ratings of evidence. The lower evidence rating for the five remaining drug classes is a result of the types of studies available (i.e., observational), relevance to the clinical question and risk of publication bias, among other criteria. However, the Beers Panel still felt a strong avoid recommendation was appropriate and important for these medications. We recommend NQF maintain endorsement of this measure (#0022).

Measure Steward/Developer Response:
N/A

- ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. Performance measurement closes the gap between evidence-based medicine and evidence-based practice. The Beers Criteria Medication List is regarded as a critically important, evidence-based guidance document to guard against the use of potentially inappropriate medications for elderly patients. It is highly utilized in the practice community to assist with appropriate medication selection, avoidance of patient harm, and improved patient outcomes in patients at least 65 years of age and older. While it is understandable for the Standing Committee to carefully evaluate the strength of the evidence behind the recommendations made by the American Geriatrics Society 2019 Beers Criteria Update Expert Panel, there are a number of reasons for the limited evidence. As an example, the low evidence may be due to the age of the medication and lack of robust effectiveness data. It is important for a performance measure like NQF 0022 to align with the consensus-based process followed in order to reduce the risk of harm and avoid conflicting information. We believe this measure aids in the prevention of medication-related harm in elderly patients. As such, we believe NQF 0022 should remain an endorsed measure in the NQF Patient Safety Portfolio.

Measure Steward/Developer Response:
N/A

- The Anticoagulation Forum (ACF) With over 12,000 members, ACF is the largest professional organization of anticoagulation management specialists in North America. The American Geriatrics Society's Beers List ("Beers List") and NQF 0022 have been important tools in driving appropriate prescribing for the elderly for years, particularly in the context of prescription drug plans. While ACF recognizes the limitations of these resources and the concerns of the Committee, we support the continued endorsement of the measure until more focused and robust measures targeting the quality and safety of antithrombotic medications (i.e., anticoagulants and antiplatelet medications) and related outcomes (avoidable bleeding and thrombotic outcomes) can be developed and implemented. The alignment of facility and health plan-focused oversight efforts is incredibly important, as together the programs promote action and attention across care settings. In our opinion, to remove NQF 0022 now would discard the valuable progress made to date and would result in a diminished focus on safe prescribing for our most vulnerable citizens across care settings. Recommendation: The Anticoagulation Forum encourages the Patient Safety Standing Committee to recommend NQF 0022 for endorsement. We also recommend and would wholeheartedly support additional efforts to develop, test, and implement new process and outcome measures focusing on the safe and effective use of antithrombotic medications.

Measure Steward/Developer Response:
N/A

Proposed Committee Response:
The Standing Committee thanks the commenters for their comments. The Standing Committee will consider this information when revoting on the Evidence criterion for this measure.

Action Item:
Review the comments that have been received and revote on the Evidence criterion for this measure.

0097: Medication Reconciliation Post-Discharge

- ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. Broadly we support calls from the Standing Committees to link care processes to outcomes in performance measurement. As it relates to the discussion by Standing Committee members on NQF 0097, we urge caution in the removal of a process measure that addresses a performance gap and mitigates potential patient harm when an outcome measure is not yet available or does not have a robust body of knowledge to merit a high ranking for scientific availability. Therefore, we do not support the removal of NQF 0097 and we request that the committee vote in favor of continued endorsement. We recognize that a "check the box" process may not be directly related to improving outcomes. We also recognize that this hasn't been robustly evaluated through study designs related to larger outcomes such as decreased rates of hospital readmission. However, over the years, systems have been developed and implemented as a result of this measure that have resulted in improved patient care.

Measure Steward/Developer Response:
N/A

- Medication errors post-discharge are a global issue. Medication reconciliation is a critical component of several widely disseminated care transitions models including the Transitional Care Model, Care Transitions Intervention, Project BOOST, and Project RED, in which pharmacists (among other clinicians) have a role to ensure positive outcomes. Medication reconciliation post-discharge is recommended by the Joint Commission National Patient Safety Goals, Agency for Healthcare Research and Quality, World Health Organization, Institute for Healthcare Improvement, and American Geriatrics Society. Studies have shown medication reconciliation alone or in combination with other post-discharge interventions can lead to improved care and reduce negative outcomes, such as medication discrepancies, medication-related problems, and hospital readmissions. Recent studies also suggest that medication reconciliation post-discharge is particularly important for vulnerable populations like older adults. Finally, given the current clinical environment with hospitals, health systems and primary care under stress due to COVID, a health plan measure of medication reconciliation post-discharge has strong face validity. Anderson et al. (2019) said it well: "In this error-rich environment, the act of medication reconciliation has strong face validity. Without it, we are left to wonder how clinicians can prescribe medications without knowing what medications a patient has already been prescribed. How would they avoid the harm of prescribing a duplicate medication? How would they be able to intervene to discontinue a hazardous medication?" We recommend NQF re-endorse this measure (#0097) to ensure patient safety and continuity of care post-discharge.

  Measure Steward/Developer Response:
  N/A

- With over 12,000 members, the Anticoagulation Forum (ACF) is the largest professional organization of anticoagulation management specialists in North America. Patients transitioning between various care settings now routinely receive medication reconciliation as a component of their care, largely due to the adoption of measures such as NQF 0097 and accreditation standards put in place for care facilities by The Joint Commission. It is particularly important that thorough and accurate medication reconciliation processes be performed for patients prescribed antithrombotic medications, as any type of error or delay in antithrombotic use can result in immediate and potentially devastating harm to patients, manifesting as either bleeding or thrombotic events. Additionally, the Anticoagulation Forum and others in the anticoagulation management community continue to develop tools and resources that build upon the minimum standards established by NQF 0097 and The Joint Commission. We therefore see the current standards as an important foundation upon which more robust, measurable processes are being built. The Anticoagulation Forum supports the retention of NQF 0097 as an endorsed measure until more focused and robust measures of effective medication reconciliation process and related outcome measures can be developed and implemented, particularly as they relate to high-risk medication classes such as antithrombotics. We also recommend and would wholeheartedly support additional efforts to develop, test, and implement new process and outcome measures focusing on the safe and consistent care transitions between settings for patients prescribed high-risk medications, such as antithrombotic agents.

  Measure Steward/Developer Response:
  N/A

- The American College of Clinical Pharmacy (ACCP) is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in patient care practice and research. Seamless transitions of care require effective

coordination, communication, and continuity as patients move through the care continuum. Fragmented care can result in increased medication errors, readmissions, and other medication-related complications. Patients moving between health care settings or providers are at increased risk of complications, including unplanned hospital readmissions and medication errors. Members of the health care team must work in concert with each other and across settings to ensure coordinated and continuous care for patients undergoing these transitions of care. Clinical pharmacists support patients during care transitions by providing clinical services designed to improve medication outcomes. The medication reconciliation process serves as a tool and opportunity to document, assess, and evaluate medications to achieve medication optimization. We encourage the Standing Committee to consider additional evidence of the impact of medication reconciliation in decreasing medication discrepancies at discharge.

Measure Steward/Developer Response:
N/A

Proposed Committee Response:
The Standing Committee thanks the commenters for their comments. The Standing Committee will consider this information when revoting on the Evidence criterion for this measure.

Action Item:
Review the comments that have been received and revote on the Evidence criterion for this measure.

0531: Patient Safety Indicator (PSI) 90: Patient Safety and Adverse Events Composite

- The FAH remains concerned with the less than desirable intraclass correlation coefficients (ICC) at the minimum sample size and the lack of inclusion of social risk factors in the risk adjustment model. The FAH does not support continued endorsement of this measure until these concerns are addressed.

Measure Steward/Developer Response:
Minimum Sample Size for Reliability:

Thank you for your comment. CMS agrees that PSI 90 (and most other outcome measures) do not generate reliable results for very small hospitals, especially when most of the component measures are missing. However, the Federation of American Hospitals may have misinterpreted Tables 6 and 7 in our Testing Attachment. In fact, 67% (using split-sample methods) and 51% (using test/retest methods across non-overlapping periods) represent the percentage of hospitals that DID meet the ICC reliability threshold of 0.6, rather than the percentage that did not. To address this issue, CMS plans to set a minimum threshold of 25 hospital discharges (starting in FY2023 using a discharge period of 7/1/19-6/30/21), aligning with the thresholds set for other CMS claims-based measures. In addition, CMS plans to require at least 7 PSI components to be available for PSI 90 score calculation. This will ensure that all hospitals have enough components to contribute at least 50% of the total weight for PSI 90. These changes will drop roughly 6% of hospitals that have very low reliability values and will yield reliability distributions that are very similar to those for all other claims-based hospital measures, including CMS' measures of 30-day mortality, 30-day readmissions, and 30-day excess days of care. The Scientific Methods Panel and the Patient Safety Standing Committee carefully considered this evidence; both voted to recommend maintenance of endorsement.

Social factors:

Thank you for your comments regarding social risk factor adjustment in CMS PSI 90, Patient Safety and Adverse Events Composite. In its submission to NQF, CMS referenced the 2020 ASPE report on Social Risk Factors and Performance in Medicare's Value-based Purchasing program but did not rely solely on the recommendations in this report. However, this report provides a sound basis for consistent HHS/CMS policy decisions with respect to adjusting for social risk factors. CMS addressed the issue of social risk factors by reporting an independent analysis of disparities for each of the component measures in PSI 90. This analysis of over 9 million discharges from over 3,200 hospitals is presented in the Evidence Attachment Tables 3-12.

Following the submission, CMS conducted parallel analyses based on dual eligibility (Medicaid + Medicare). In summary, some racial/ethnic and dual eligibility disparities exist for the PSI 90 component measures, but there is no consistent pattern across these components. This finding is not surprising as the PSI 90 component measures focus exclusively on hospital-acquired complications of care. Across racial-ethnic categories, the Medicare FFS data show at least 20% higher adjusted rates among Black patients, relative to White patients, for only 3 of 10 PSI components (PSIs 03, 12, 15).1 Comparing Hispanic patients with White patients, Hispanics had at least 20% higher adjusted PSI rates only for 2 of 10 PSI components (PSIs 14, 15). For the majority of PSI 90 component measures, Black and Hispanic patients had lower or similar adjusted rates, compared with White patients. Similarly, fully dual-eligible beneficiaries had at least 20% higher adjusted PSI rates, relative to non-dual-eligible beneficiaries, for only 3 of 10 PSI 90 components (PSIs 03, 13, 14).2 As this is a measure of potentially preventable patient harms, it is important that these differences not be adjusted away. Higher risk patients should be more closely monitored with more intense prevention strategies to minimize the risk of adverse outcomes. There are also ethical considerations involved in risk adjusting complication rates by race or socioeconomic status. These considerations are relevant, no matter the number of accountability purposes or applications in which a measure is used.

CMS agrees with the commenters regarding the value of linked data from the American Community Survey, will follow ASPE's ongoing work in this domain, and will conduct further testing as additional data on social risk factors become available. At this time, ASPE's analysis remains the most comprehensive and thorough assessment of the role of social risk factors in the measures used by CMS.

1. Four (4) components using v11.0 software (PSIs 03, 10, 12, 15)

2. PSIs 03 and 13 in both tested years (7/1/2017-6/30/2018, 7/1/2018-6/30/2019), PSI 10 in the first year only, PSI 14 in the second year only."

- The American Medical Association (AMA) continues to strongly oppose the endorsement of this measure. This measure must require higher case minimums to allow the overwhelming majority of hospitals to achieve an ICC of 0.6 or higher. The fact that only 67% of all hospitals were able to achieve an intraclass correlation coefficients of =>0.6 in the split sample testing and only 51% in the test-retest using 24 months of data along with the lack of inclusion of social risk factors in the risk adjustment model leads us to believe that the measure does not meet the scientific acceptability criteria.

Measure Steward/Developer Response:
Minimum Sample Size for Reliability:

Thank you for your comment. CMS agrees that PSI 90 (and most other outcome measures) do not generate reliable results for very small hospitals, especially when most of the component

measures are missing. However, the Federation of American Hospitals may have misinterpreted Tables 6 and 7 in our Testing Attachment. In fact, 67% (using split-sample methods) and 51% (using test/retest methods across non-overlapping periods) represent the percentage of hospitals that DID meet the ICC reliability threshold of 0.6, rather than the percentage that did not. To address this issue, CMS plans to set a minimum threshold of 25 hospital discharges (starting in FY2023 using a discharge period of 7/1/19-6/30/21), aligning with the thresholds set for other CMS claims-based measures. In addition, CMS plans to require at least 7 PSI components to be available for PSI 90 score calculation. This will ensure that all hospitals have enough components to contribute at least 50% of the total weight for PSI 90. These changes will drop roughly 6% of hospitals that have very low reliability values and will yield reliability distributions that are very similar to those for all other claims-based hospital measures, including CMS' measures of 30-day mortality, 30-day readmissions, and 30-day excess days of care. The Scientific Methods Panel and the Patient Safety Standing Committee carefully considered this evidence; both voted to recommend maintenance of endorsement.

Social factors:

Thank you for your comments regarding social risk factor adjustment in CMS PSI 90, Patient Safety and Adverse Events Composite. In its submission to NQF, CMS referenced the 2020 ASPE report on Social Risk Factors and Performance in Medicare's Value-based Purchasing program but did not rely solely on the recommendations in this report. However, this report provides a sound basis for consistent HHS/CMS policy decisions with respect to adjusting for social risk factors. CMS addressed the issue of social risk factors by reporting an independent analysis of disparities for each of the component measures in PSI 90. This analysis of over 9 million discharges from over 3,200 hospitals is presented in the Evidence Attachment Tables 3-12.

Following the submission, CMS conducted parallel analyses based on dual eligibility (Medicaid + Medicare). In summary, some racial/ethnic and dual eligibility disparities exist for the PSI 90 component measures, but there is no consistent pattern across these components. This finding is not surprising as the PSI 90 component measures focus exclusively on hospital-acquired complications of care. Across racial-ethnic categories, the Medicare FFS data show at least 20% higher adjusted rates among Black patients, relative to White patients, for only 3 of 10 PSI components (PSIs 03, 12, 15).1 Comparing Hispanic patients with White patients, Hispanics had at least 20% higher adjusted PSI rates only for 2 of 10 PSI components (PSIs 14, 15). For the majority of PSI 90 component measures, Black and Hispanic patients had lower or similar adjusted rates, compared with White patients. Similarly, fully dual-eligible beneficiaries had at least 20% higher adjusted PSI rates, relative to non-dual-eligible beneficiaries, for only 3 of 10 PSI 90 components (PSIs 03, 13, 14).2 As this is a measure of potentially preventable patient harms, it is important that these differences not be adjusted away. Higher risk patients should be more closely monitored with more intense prevention strategies to minimize the risk of adverse outcomes. There are also ethical considerations involved in risk adjusting complication rates by race or socioeconomic status. These considerations are relevant, no matter the number of accountability purposes or applications in which a measure is used.

CMS agrees with the commenters regarding the value of linked data from the American Community Survey, will follow ASPE's ongoing work in this domain, and will conduct further testing as additional data on social risk factors become available. At this time, ASPE's analysis remains the most comprehensive and thorough assessment of the role of social risk factors in the measures used by CMS.

1. Four (4) components using v11.0 software (PSIs 03, 10, 12, 15)

2. PSIs 03 and 13 in both tested years (7/1/2017-6/30/2018, 7/1/2018-6/30/2019), PSI 10 in the first year only, PSI 14 in the second year only."

- Opposition to the composite measure for PSI 90 specifically because of the continued inclusion of Post-Surgical Hip Fracture as the only representative measure of falls with injury. Post-surgical hip fractures are so rare, that the weighted contribution of falls with injury, is underrepresented in the composite measure. Falls with injury continue to be in the top reported harm events reported in hospitals, and in the last report of TJC's sentinel events, was the top adverse event. It was a mistake for the NQF Patient Safety Measures to not continue to endorse ANA's Falls and Falls with Injury Measures just because of risk adjustment issues, when risk adjusting by unit-type remains the risk adjustment method for NDNQI data reports. The measure, without the Falls With Harm component underestimates the amount of harm occurring in hospitals, which should be risk adjusted by age groups. The percent of patients 65 and older, 75-84, and 85 and older is increasing in hospitals. Older adults who fall in hospitals, esp. 75 and older, are at greatest risk for loss of function and loss of life when they fall. This work dates to 2008 with the Department of Veterans Affairs and IHI's Reducing Serious Injuries from Falls on Medical Surgical Units. With all the CMS funding launched with the Hospital Engagement Networks, the first round of hospital funding to reduce harm in hospitals, falls with injury have continued to under achieve expected goals. For CMS to continue to exclude falls with injury in this measure, mis-represents to the public that harm that continues to occur in hospitals. (Patricia A. Quigley, PhD, MPH, APRN, CRRN, FAAN, FAANP, FARN, Fall and Fall Injury Prevention Expert; Prior Member of the NQF Patient Safety Committee, Patient Safety Complications Committee, and Federal Partnership for Patients; Now an NQF Member)

Measure Steward/Developer Response:
Thank you for your comment regarding the PSI 08 (In-Hospital Fall with Hip Fracture Rate) component of CMS PSI 90 (Patient Safety and Adverse Events Composite). CMS agrees that falls with injury are an important cause of harm in acute care hospitals. First, as the measure title suggests, the denominator for this measure has already been expanded to include both medical and surgical adult patients 18 years and older. PSI 08 is no longer limited to post-surgical patients. This expanded version was discussed and recommended unanimously for endorsement by the Patient Safety Standing Committee. In addition, in the forthcoming release, the denominator was further expanded by removing exclusion criteria that were not well justified on clinical and empirical grounds (e.g., principal diagnosis of seizure, syncope, stroke, coma, cardiac arrest, poisoning, trauma, delirium, psychosis, anoxic brain injury, cancer). These admission-related factors, age (in 5-year categories), and numerous comorbidities are included in the PSI 08 risk-adjustment model, which has excellent discrimination (c=0.871) and calibration. CMS agrees that further expansion of PSI 08, to include other significant harms resulting from falls, would help to drive further improvements in patient safety. These efforts are currently underway, and will be reflected in future measure submissions to NQF.

Proposed Committee Response:
The Standing Committee thanks the commenters for their comments. The Standing Committee and the NQF Scientific Methods Panel have previously considered the specifications and scientific acceptability of this measure, including the reliability testing and risk adjustment models. In evaluating this measure against NQF's endorsement criteria, the Standing Committee determined to recommend this measure for endorsement.

Action Item:
Review the comments received and determine whether to accept the proposed Standing Committee response.

2993: Potentially Harmful Drug-Disease Interactions in Older Adults (DDE)

- ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. ASHP supports the Standing Committee in their decision to continue the endorsement of NQF 2993. Drug-disease interactions in the setting of a history of falls, dementia, and chronic kidney disease warrant performance measurement and continued prioritization in outpatient settings.

  Measure Steward/Developer Response:
  N/A

  Proposed Committee Response:
  The Standing Committee thanks the commenter for their comment.

  Action Item:
  No action needed.

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 Standing Committee's recommendations. Four NQF members provided their expressions of support: See Appendix A.

Appendix A: NQF Member Expression of Support Results

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

0022: Use of High-Risk Medications in Older Adults (DAE) (National Committee for Quality Assurance)

Member Council	Support	Do Not Support	Total
Health Professional	1	0	1
QMRI	1	0	1

0097: Medication Reconciliation Post-Discharge (National Committee for Quality Assurance)

Member Council	Support	Do Not Support	Total
Health Professional	1	0	1
QMRI	1	0	1

0468: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following pneumonia hospitalization (Centers for Medicare & Medicaid Services / Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE))

Member Council	Support	Do Not Support	Total
Health Professional	0	1	1

0531: Patient Safety Indicator (PSI) 90: Patient Safety and Adverse Events Composite (Centers for Medicare & Medicaid Services / IMPAQ International)

Member Council	Support	Do Not Support	Total
Health Professional	0	2	2

1893: Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization (Centers for Medicare & Medicaid Services / Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE))

Member Council	Support	Do Not Support	Total
Health Professional	0	1	1

2993: Potentially Harmful Drug-Disease Interactions in Older Adults (DDE) (National Committee for Quality Assurance)

Member Council	Support	Do Not Support	Total
Health Professional	1	0	1