NATIONAL QUALITY FORUM

Memo

May 3, 2018

To: Surgery 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 Surgery Standing Committee will meet via web meeting on May 3, 2018 from 3:00-5:00 pm 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:

Committee Member dial-in #: 855-599-0737 (*NO CONFERENCE CODE REQUIRED)*
Web Link: http://nqf.commpartners.com/se/Rd/Rg.aspx?854402
Registration Link: http://nqf.commpartners.com/se/Rd/Rg.aspx?854402

Background

This report reflects the review of measures in the Fall 2017 cycle for the NQF's surgery endorsement project. The measures in the surgery portfolio project focus on key surgical care processes across an array of procedure types that include outcomes for general and subspecialty surgical procedures, such as cardiac, orthopedic, ophthalmological, and vascular surgeries and procedures, and all phases of perioperative care. For this cycle of the project, the measures evaluated were focused on lung resection and lobectomy for lung cancer and

hospital visits following general surgery procedures.

The 24-member Surgery Standing Committee has been charged with overseeing the NQF Surgery measure portfolio, evaluating both newly submitted and previously endorsed measures against NQF's measure evaluation criteria, identifying gaps in the measurement portfolio, and providing feedback on how the portfolio should evolve.

On February 1, and February 6, 2018, the Surgery Standing Committee evaluated three measures that included one maintenance measure and two new measures. The Committee recommended endorsement for all three measures:

- 1790 Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer
- 3294 Lobectomy for Lung Cancer Composite Score
- 3357 Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers

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 December 11, 2017 to January 24, 2018 for the measures under review. No pre-evaluation comments were submitted.

Post-evaluation Comments

The draft report was posted on the project webpage for public and NQF member comment on March 14, 2018 for 30 calendar days. During this commenting period, NQF received two comments from two member organizations and one public comment.

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

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.

We will use this call to consider the three measure-specific comments discussed below. Please note that the organization of the comments into major topic areas is not an attempt to limit 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 Deposition

Measure-Specific Comments

3357 Facility Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers

Generally, the three comments received addressed measure specifications, measure validity, sociodemographic risk adjustment, and whether the measure provides information about meaningful differences in performance and is actionable in order to improve the quality of surgical care. Commenters questioned the inclusion of skin procedures in the measure specifications because general surgeons do not routinely perform these procedures. Commenters also questioned whether skin procedures were included to boost low case volume. Two comments noted that the measure should be risk adjusted for social risk factors, such as socioeconomic status (SES), for providers who serve low SES clients. One commenter pointed out that unplanned visits are not always in the surgeon's control and could be related to issues of access to care. Submitted comments also noted that the measure is "topped out" and does not provide enough variation in performance to discern quality of care.

Measure Steward/Developer Response:

Measure Outcome - The commenter stated that the "readmission measure is not a good proxy for driving improvement in surgical care." We would like to clarify that the measure under review by the NQF (NQF ID 3357) is not a readmission measure. The measure's outcome is any unplanned hospital visit, defined as an emergency department (ED) visit, observation stay, or unplanned inpatient admission, occurring within 7 days of a general surgery procedure performed at an ambulatory surgical center (ASC). The outcome of hospital visits is the focus of this measure because it is a broad, patient-centered outcome that captures the full range of hospital visits resulting from adverse events or poor care coordination following an ASC general surgery procedure. This measure's goal is to assess and illuminate variation in risk-adjusted hospital visits following surgery, for quality improvement and public reporting.

Alignment with Registry-Based Measures - The commenter "believes that surgical measurement should be built on four key principles: 1) setting the standards, 2) building

the right infrastructure, 3) using the right data, and 4) verifying with outside experts," and advocates that ASC measures "include standards-based facility-level verification programs, patient reported experience (PRE) and outcome (PRO) measures, and traditional quality measures including registry and claims-based measures."

This 7-day hospital visit measure fits within the above framework. It increases surgeon and ASC accountability for and awareness of patient outcomes during the post-surgical period, and provides facilities with patient-level data on outcomes to inform quality improvement that ASCs currently lack. The availability of linkable Medicare claims data to calculate the risk-adjusted measure and link patient outcomes, procedure, and risk factor data across settings makes this a low-burden measure that can provide valuable information and complement registry-based, surgery-society developed measures such as PROs.

We would like to further clarify that our measure development process is aligned with the four key principles that the commenter identified as foundational for surgical quality measurement. We built the measure using standards for quality measure development set forth by CMS in its Measure Management System Blueprint. The measure was developed with input from general surgery consultants, a national Technical Expert Panel, and the public.

Usability and Actionable Information - Two commenters expressed concern that the measure would be of limited utility, and that the information it provides is not actionable.

For ASCs, we believe measuring and publicly reporting claims-based, risk-adjusted measure scores will encourage ASCs to engage in quality improvement and lead to better patient care over time. Further, CMS plans to implement the measure to optimize its usability. Prior to public reporting, CMS anticipates providing claims-detail and facility-specific reports, as the Agency does for other outcome measures. These reports will allow ASCs to see patient 7-day outcomes that are currently not visible to them. This information will help ASCs understand their performance, inform quality improvement efforts, and improve the care they provide to patients.

Variation in Performance Scores and Identification of Outliers - All three commenters expressed their view that there is not enough variation in the measure results to show meaningful differences between facilities. One commenter expressed concern that the measure identifies relatively few outliers as better or worse than expected.

We appreciate the commenters' concerns. The measure score results, however, do present a clinically meaningful range in risk-adjusted outcome rates. As presented in the public comment technical report using Medicare FFS CY 2015 data, we found that the facility measures scores ranged from 0.94% to 4.55%, with a median risk-standardized hospital visit rate of 2.19% (the 25th and 75th percentiles were 2.03% and 2.46%, respectively). The variation in these rates provides a quality signal, and reporting facility-level measure scores will improve transparency and promote quality improvement.

To assist consumers with interpreting the measure, we provide a descriptive category of facility quality (better than, worse than, or no different than the national rate); to provide ASCs and other users with richer insight into performance, we provide the estimated 7-day hospital visit rate and the 95% interval estimate (uncertainty estimate) around that rate. As the commenters pointed out, the descriptive approach categorizes relatively few facilities as outliers. The approach to categorizing facility outliers is very conservative by design. It uses 95% confidence interval (uncertainty) estimates to identify outliers.

Measuring quality of care associated with general surgery procedures performed at ASCs would bring awareness to ASCs and provide valuable data to patients. As intended, we expect this measure will promote patient-centered improvement in care provided at ASCs, because measurement coupled with transparency will make visible, for the first time, the rate of hospital visits after general surgery ASC procedures to both patients and ASCs.

Emergency Department (ED) Visits and Observation Stays - One commenter was concerned that the planned admissions algorithm was not applied to ED visits or hospital observation stays, and that counting all ED visits as unplanned did not account for lack of "patient access to care in the desirable setting." As the commenter noted, we have previously stated that while we understand that the ED and hospital observation setting may be used for planned care at times, the measure is structured to count these events because these settings are not usually a desirable setting for planned care from the patient's point of view.

Also, ASCs are expected to limit their cases to those that can be safely performed outside the hospital setting. Higher rates of serious but potentially preventable complications that result in ED visits and observation stays may be a sign of poorer quality ASC care. ASCs can reduce the likelihood of these serious complications by emphasizing patient safety and reducing rates of complications or harm events, and by discharge planning that anticipates the need for potential office-based follow up care.

Measure Cohort - One commenter noted that this measure "is meant to capture all other routinely performed outpatient surgical procedures," unlike the other measures in CMS's ASCQR program that focus on colonoscopy, orthopedic, or urology procedures. For this measure, we clarify that we targeted procedures that fall within the scope of general surgery, including those performed by other surgical specialists. We combined these procedures because they share the risk of post-surgery hospital visits within 7 days, they share common reasons for return to the hospital, and the risk of hospital visits following these procedures can be mitigated through similar strategies.

Additionally, three commenters expressed concerns that the measure includes many skin and plastic surgery procedures. We understand the commenters' concerns that over half the procedures in the cohort are skin procedures and concern that these procedures were included to increase sample size. The commenters also stated that many of the included procedures are performed by surgeons other than general surgeons.

As noted above, we included procedures within the scope of practice of general surgery even though these procedures are often performed by other subspecialists because they share common features that allow us to combine them for assessing quality. However, the commenters are correct that in addition to general surgeons, other types of surgeons and non-surgical specialists perform skin and other procedures included in the cohort. As we clarified above, we included these procedures in a single measure because the procedures share (1) a risk of post-surgery hospital visits within 7 days and (2) relatively similar reasons for return to the hospital. Members of our TEP also felt the care practices that would best lower the risk of hospital visits were similar across these procedures. Procedural volume was not a criterion for inclusion of procedures in the cohort.

Further, we identified and refined the group of procedures to include in the cohort through multi-stakeholder review and input from a national TEP, general surgery consultants, and the public. For example, in light of comments receive on the measure during measure development public comment, we re-reviewed all of the individual CPT codes within CCS categories and removed 15 individual procedures (CPT® codes) from the measure that were outside the scope of general surgery practice.

Adjustment for Social Risk Factors -Two commenters expressed concern that the measure is not adjusted for social risk factors.

As previously acknowledged in the conceptual model we presented in the NQF application, we agree that patients' socioeconomic status (SES) affects health and health outcomes in important ways.

Our intent when developing and testing the measure was to be responsive to the NQF guidelines for measure developers on SES. We therefore examined three patient-level indicators of social risk that are reliably available for all Medicare beneficiaries: 1) Medicare-Medicaid dual eligibility, 2) race, and 3) the AHRQ SES Index. The variables used are aligned with those the National Academy of Medicine committee identified as available for use in outcome measures. We examined whether these factors were associated with increased risk in hospital visits after adjusting for other risk factors and evaluated the impact of social risk factors on ASC-level measure scores.

While including each of these risk factors in our models indicated a statistically significant association after controlling for other risk-adjusters, results showed that the effect of social risk factors on hospital visit rates in the fully adjusted model was significant but small. Additionally, inclusion of these variables did not change ASCs' risk-standardized hospital visit ratios (RSHVRs) or their performance on the measures. Correlation coefficients between RSHVRs with and without adjustment for these factors were near 1 (0.998, 1.000, and 0.999 for dual-eligible, African-American, and low SES patients, respectively) and mean differences in RSHVRs were near zero (0.0000, -0.0001, and -0.0002 for dual-eligible, African-American, and low SES patients, respectively).

In addition, we examined the relationship between the proportion of low SES patients and the facility-level score, focusing on facilities with the highest proportion of dual

eligible patients (fourth quartile). This analysis did not show a clear relationship between the proportion of low SES patients and the facility-level score (Pearson correlation coefficient = -0.17).

Based on these findings, and a consideration of how social risk factors affect patients in the ambulatory setting and the importance of efforts to address all patients' needs, CMS decided to not adjust the models for these social risk factors; not adjusting is not likely to lead to unintended consequences, or burden providers that serve low SES patients, and adjusting may mask quality differences. However, once the measure is implemented, CMS will monitor this measure, as with others, for unintended consequences related to disparities.

Finally, we acknowledge the importance of optimizing measures to incentivize high quality care for all while ensuring providers caring for low SES patients are not disadvantaged on the measures. CORE, with CMS, is exploring alternative modeling approaches that better illuminate how ASCs and their patients contribute to SES-related risks, and will continue to explore incorporating social risk factors into quality measures.

Attribution of Outcomes - We appreciate the commenter's continued review of the top reasons for any hospital visit within 7 days of general surgery procedures.

As previously clarified, the diagnoses referred to by the commenter (Table 4 of measure documentation) can occur during an admission, ED visit, or observation stay. If they occur during an admission, then all but one type (acquired absence of breast and nipple) are identified as planned admissions and are not counted in the measure outcome. If these diagnoses (including cancer diagnoses) occur as part of an ED visit or observation stay, they are included in the measure outcome because ED visits and observation stays are not routinely used for planned care. We understand that the ED and hospital observation setting may be used for planned care at times, but the measure is structured to count these events because these settings are not usually a desirable setting for planned care from the patient's point of view.

CORE is committed to evaluating whether refining the CMS planned admission algorithm will better capture planned admissions for the diagnoses flagged by comments. As such, during measure reevaluation, CORE will consider updating the planned admission algorithm to include acquired absence of breast and nipple so that admissions with this diagnosis would not be counted in the measure outcome.

Measure Title - We appreciate the commenter's suggestion to rename the measure. We have already renamed the measure to address this concern. The measure was previously named "Hospital Visits After General Surgery Ambulatory Surgical Center Procedures," and we revised its title to be "Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers." Our intent was to emphasize the scope of the procedures included in the measure cohort rather than the types of specialists performing them. The scope of the measure was defined by the scope of practice of general surgeons. Thus, we have chosen not to include "skin procedures" or "plastic repair" in the title given that many types of procedures in the

measure are performed by both general surgeons and other specialists, and including one specific procedure type in the title would make the scope of the measure less clear. We believe the measure title accurately reflects what it assesses. CMS welcomes continued suggestions on the best name for the measure.

Low ASC Case Volumes - The commenter expressed concern that this measure would provide insufficient information for low-volume facilities. We understand the commenter's concern that the measure would not provide sufficient information about the quality of care in individual low-volume facilities. For this measure, as is done for other risk-adjusted outcome measures, CMS will set minimum-volume requirements for reporting and only report scores for ASCs that have an adequate number of cases to generate reliable estimates. For example, for publicly reported outcome measures such as CMS's hospital readmission measures, CMS implemented minimum volume requirements for reporting.

The commenters also expressed concern about CMS implementing this measure using an inadequate amount of data. The commenter referenced CMS's use of only 1 year of claims data for implementation of another risk-adjusted outcome measure (ASC-12: Facility Seven-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy) in the ASCQR program, instead of 3 years of claims data. For this general surgery measure, CMS will consider using multiple years of claims data for public reporting. We calculated measure score (test, retest) reliability for a 2-year reporting period and found that the agreement (intraclass coefficient) between the two RSHVR values for each ASC was 0.526, indicating moderate measure score reliability. NQF committees consider their evaluation criteria to be rigorous, which state that moderate or high reliability is typically required for endorsement.

Prior to measure implementation, CMS will evaluate the amount of data required for reliable measure score calculation, and determine the number of years of data to use, weighing the tradeoffs between having an adequate number of cases for the greatest number of facilities and ensuring data used are timely.

Proposed Committee Response:

Thank you for your comment. The Committee will review these comments during their deliberations on the Post-Comment Call scheduled on May 3, 2018.

NQF Response:

Thank you for your comment. The preliminary analysis included a summary from the MAP report. NQF is providing the Standing Committee with the 10 comments submitted to the MAP Hospital Workgroup for review prior to the Post-Comment Call scheduled on May 3, 2018.

Action Item:

The Committee will review the comments previously submitted to the MAP Hospital Workgroup **prior** to the Post-Comment Call scheduled on May 3, 2018. On the Post-Comment Call, the Committee will discuss the commenters' concerns and the developer's response.

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 members provided their expressions of non-support: See Appendix A.

Appendix A: NQF Member Expression of Support Results

Two NQF members provided their expressions of support. Results for each measure are provided below.

1790: Risk-Adjusted Morbidity and Mortality for Lung Resection for Lung Cancer (Society of Thoracic Surgeons)

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

3294: STS Lobectomy for Lung Cancer Composite Score (Society of Thoracic Surgeons)

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

3357: Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (Centers for Medicare & Medicaid Services/Yale CORE)

Member Council	Support	Do Not Support	Total
Consumer	0	0	0
Health Plan	0	0	0

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