TO: National Quality Forum and Pulmonary Steering Committee

FROM: Bob Rehm, Assistant Vice President, Performance Measurement
Ben Hamlin, Director, Performance Measurement
Dawn Alayon, Senior Health Care Analyst, Performance Measurement

DATE: May 30, 2012

RE: Request for Reconsideration of Measure 0549: Pharmacotherapy Management of COPD Exacerbation (PCE)

On March 21, 2012, the National Quality Forum (NQF) Pulmonary Steering Committee (SC) reviewed the currently endorsed NQF measure 0549: Pharmacotherapy Management of COPD Exacerbation (PCE), an administrative claims-based health plan measure assessing the percentage of COPD exacerbations for members 40 years of age and older for which appropriate medications were dispensed.

Two rates are reported.

1. Dispensed a systemic corticosteroid within 14 days of the event
2. Dispensed a bronchodilator within 30 days of the event

Measure 0549 was the 22nd of 23 measures evaluated during the day and following strong affirmative votes in the three sub-criteria of Importance and the first Scientific Acceptability sub-criterion of Reliability, the Pulmonary Steering Committee's next vote on the sub-criterion of Validity received a very close vote resulting in suspension of further discussion and moving on to the last measure of the day. Given the volume of measures reviewed, the nature of the questions raised by the SC, and the observed and self-characterized fatigue on the part of the SC, we believe additional consideration at this point of the SC review, with leadership and guidance from the NQF staff would have been appropriate for a measure in broad national use and publicly reported. We have observed in several other steering committees that NQF leadership has offered additional guidance when measures have unexpectedly hit a snag, or a vote is close.

SC Voting Record for NQF Measure 0549 March 21, 2012

Importance	**H**	**M**	**L**	**I**	
1a – High Impact	15	3	0	0	Pass 18-0
1b – Performance Gap	2	13	2	1	Pass 15-3
	Y	**N**	**I**		
1c – Evidence to support measure	15	1	2		Pass 16-2
Scientific Acceptability	**H**	**M**	**L**	**I**	
2a - Reliability	1	11	5	1	Pass 12-6
2b - Validity	0	7	8	2	Not Pass- review terminated
Usability	**H**	**M**	**L**	**I**	
3a-b					No vote
Feasibility	**H**	**M**	**L**	**I**	
4a-d					No vote
Overall Suitability	**Y**	**N**			
Pass/Fail					No vote

The following morning, NCQA provided additional information in response to questions that were raised during the SC review and requested that NQF staff review both the vote and the discussion during the measure review and reconsider the close SC vote on Validity. In response NQF leadership directly informed the SC that they would be receiving additional information from NCQA that may clarify SC concerns. Thirty days later

following an additional request for follow-up, NQF staff responded that a large majority of SC members reaffirmed the original evaluation on the measure. The Committee appreciated the additional information provided; however, they did not feel that the information addressed the issues they had raised.

In the intervening period since the SC meeting, NCQA reviewed the technical draft report, the WG and SC audio recordings and transcripts. Based on this review, we found that SC members were discussing issues un-related to the sub-criteria under review. NCQA would like this opportunity to address those issues and respectfully requests that the NQF SC reconsider the measure based on the clarifications provided.

Several questions about the measure logic were posed by the SC during their deliberations on the Importance sub-criteria including:

1. ***Does 0549 capture samples providing in the ED or hospital?*** There are currently no mechanisms for capturing the provision of samples in any setting, whether that is a health plan, a hospital, ED or physician office. NCQA knows of no NQF-endorsed measure that includes a specification that includes capturing of drug samples. In contrast to many NQF-endorsed measures that use "prescribed" data, all NCQA medication-related measures rely solely on dispensed drug information. A survey of several prominent ED physicians was conducted following this meeting and there was general agreement that this practice is almost non-existent for the types of medications required for this measure.
2. ***Does 0549 capture prescriptions dispensed in the ED?*** Yes-ED medication events are submitted by the hospital/ED and paid by the health plan and therefore captured in the paid pharmacy claims data, the same way as any dispensed ambulatory medications.
3. ***How does 0549 capture listed medications that are in current use (active prescription) at the time of the event? Does 0549 require a look back period?*** Health plans look back for active prescriptions. If a health plan member has a valid prescription that persists through the date of the exacerbation this is used to count the person as numerator compliant. Health plans reporting this measure are positively rewarded for capturing active prescriptions that indicate numerator compliance. With over 75 HEDIS measures reported by health plans, NCQA has evolved measure specifications that are feasible by a wide range of reporting entities, are audited and have demonstrated broad acceptance in the marketplace.

During the discussion period for Importance and all its sub-criteria, the SC discussion focused exclusively on the sub-criteria of Validity with no further discussion of this measure's high impact, performance gap, and evidence. Prior to the Validity vote, Dr. Stephen Grossbart, the SC Co-Chair, commented that this sub-criterion received a moderate vote from the WG and also noted that the Validity concerns raised during the prior discussion were not raised during the initial review. As reflected in the NQF measure submission form, the field testing demonstrated that this measure was able to capture COPD exacerbations in administrative claims data, validating the denominator data elements (i.e. patients with COPD exacerbations) and the numerator data elements (i.e. patients treated with inhaled bronchodilator while in the ED and patients given systemic corticosteroids while in the ED).

Our review of the SC discussions captured by meeting recordings and the subsequent voting concludes that the SC members discussion prior to each sub-criterion section and vote were focused on issues not related to the specific sub-criterion and therefore we are concerned that the SC may not have been evaluating measure 0549 against the criteria for which they were voting. This deviation from normal steering committee practice resulted in this measure not continuing for the SC vote on Usability, Feasibility and overall suitability for continued NQF endorsement. Combined with the other issues raised, NCQA believes that due to these process issues, measure 0549 warrants further review and consideration.

Addendum: NCQA Measure, Data Submission and Auditing Processes

Background**:** NQF measure #0549 has been part of the HEDIS measure set since 2008. Because of NCQA's stringent data collection and auditing process, the data submitted to NCQA for HEDIS Health Plan reporting is of the highest quality and validity. NCQA has evaluated the measure for face validity through the Respiratory Measurement Advisory Panel (RMAP), an advisory body of clinicians and methodological experts (Dr. Kevin Weiss served as Chair of this panel from 2006-2009 and was involved in the initial development and testing of measure 0549). The RMAP includes representatives from key stakeholder groups, including the CDC, pulmonologists, pharmacologists, health service researchers and healthcare delivery organizations. Following NCQA's 30 day public comment period, review of the field testing results and RMAP recommendations, the Committee on Performance Measurement (CPM) approved the specification for inclusion in HEDIS.

Once a measure is included in the HEDIS Health Plan measurement set, NCQA requires a rigid data submission and auditing process for all HEDIS measures.

HEDIS Data Submission Process: NCQA collects HEDIS data directly from Health Plan Organizations and Preferred Provider Organizations for multiple purposes via the Health Organization Questionnaire (HOQ) and HEDIS non-survey data through the Interactive Data Submission System (IDSS).

As an administrative claims-based, health plan measure, this measure can only capture medications that have been dispensed.

NCQA Auditing Process: NCQA recognizes that, despite the clear specifications defined for HEDIS measures, data collection and calculation methods may vary, and other errors may taint the results, diminishing the usefulness of HEDIS data for managed care organization (MCO) comparison. In order for HEDIS to reach its full potential, NCQA conducts an independent audit of HEDIS collection and reporting processes, as well as an audit of the data which are manipulated by those processes, in order to verify that HEDIS specifications are met. NCQA has developed a precise, standardized methodology for verifying the integrity of HEDIS collection and calculation processes through a two-part program consisting of an overall information systems capabilities assessment (IS standards) followed by an evaluation of the MCO´s ability to comply with HEDIS specifications (HD standards). NCQA-certified auditors using standard audit methodologies help enable purchasers to make more reliable "apples-to-apples" comparisons between health plans.

The HEDIS Compliance Audit addresses the following functions:

1) information practices and control procedures
2) sampling methods and procedures
3) data integrity
4) compliance with HEDIS specifications
5) analytic file production
6) reporting and documentation

June 5, 2012

Interim President and CEO
National Quality Forum
600 13th Street, NW, Suite 500 North
Washington, DC 20005

SUBJECT: Comments Regarding the Pulmonary Maintenance Review Project

Dear Interim CEO:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 42,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the National Quality Forum's (NQF) Pulmonary Maintenance Review project. Reviewing measures that have previously been endorsed is one of the fundamental tenants of measure development and we commend the NQF for continually holding all developers to this high standard. Recognizing the current state of science and medicine and how advances alter our fundamental delivery of care is something that measures must be responsive to. Our comments on the measures under review are included below.

Hospital 30-day, all cause, risk-standardized measures
There are a total of four measures in this pulmonary maintenance review project that are developed by Yale:

1. Maintenance Review: Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations (0506);
2. Maintenance Review: Thirty-day all-cause risk standardized mortality rate following pneumonia hospitalizations (0468);
3. First-time Endorsement: Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations (1891); and
4. First-time Endorsement: Thirty-day all-cause risk standardized mortality rate following COPD hospitalizations (1893).

Failure to adjust for factors beyond the hospital's control. These four measures, along with all of Yale's 30-day all cause risk standardized measures, consistently fail to adjust for factors beyond a hospital's control. Changes need to be made to these measures to properly stratify for patient characteristics (dual eligible status and race/ethnicity) and exclude extreme circumstances (transplant, end-stage renal disease, burn, trauma, psychosis and substance abuse). Further, these measures must address patient compliance with treatment plans and the quality of post-acute care provided to the patient.

The fact that these measures are "all-cause" means they will include readmissions and deaths that have nothing to do with the specific condition associated with the measure. A COPD patient could be readmitted/die from a fall, a car accident, or an unrelated condition not risk-adjusted in the measure. However, that readmission/death will still be included against the hospital in these measures. For these reasons, the hospital 30-day, all cause, risk-standardized measures

that are publicly reported provide information that is unsuitable for medical decision-making by consumers, because patients cannot parse out the many variables necessary to truly assess a hospital's performance.

Reliability. On February 13 CMS released a reliability study[A], required by the ACA, for claims-based measures. The study shows that the majority of claims-based measures currently used in CMS's programs are unreliable. Among the measures included in the study was the pneumonia mortality measure. The CMS study states that "reliability of an outcome measure is the extent to which variation in the measure is due to variation in quality of care rather than random variation due to the sample of cases observed. The statistical concept of reliability (R) used to determine the minimum case size for a particular measure is whether a hospital's ranking on that measure, compared to its performance in other periods or compared to other hospitals, is likely to be the same if we take repeated samples of the hospital's own cases. R depends on the rate's variance between hospitals, the variance of the rate within a hospital's own cases, and the number of discharges from a given hospital." Table 1 below includes the information from the study on the pneumonia mortality measure.

Table 1 – Reliability of Pneumonia Mortality Measure

Measure	**6 Months**		**12 Months**		**18 Months**		**24 Months**	
	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**
PN Mortality (R = 0.4 with 211 cases)	0.11	1	0.19	8	0.27	22	0.32	35
* Reliability of measure of hospital of median case size **Proportion of hospitals with case size large enough that R ≥ 0.4								

The CMS study indicates that "R = 0.4 is considered to be the lower limit of 'moderate' reliability." Yale sets its reliability rates at 0.4 for all of its hospital 30-day, all cause, risk-standardized measures. "The lower limit of moderate reliability" is not sufficient for NQF-endorsement. CMS's standard[B] for non-claims-based measures is R = 0.75. Further, we note that in order to achieve R = 0.4 for the pneumonia mortality measure, CMS recommends that a minimum of 211 cases are needed. The current minimum threshold for the Yale pneumonia measure is 25 cases—a major difference. Though the measure developer uses 36-months of data and this study does not address 36- months of data, we still do not believe this measure is reliable. **At a minimum, we urge the steering committee to request this reliability data of the measure developer for both the pneumonia and COPD mortality measures.**

KNG, an independent research firm, has replicated[B] CMS's reliability study for both the pneumonia and COPD readmission measures. The results of this analysis are included in Table 2, below.

Table 2 – Reliability of Pneumonia and COPD Readmission Measures

Measure	12 Months		24 Months		36 Months	
	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**	Median* Reliability	% of Hospitals R ≥ 0.4**
PN Readmission (R = 0.4 with 121 cases)	0.28	21%	0.43	57%	0.53	75%
PN Readmission (R = 0.7 with 421 cases)		0%		5%		16%
COPD Readmission (R = 0.4 with 154 cases)	0.22	14%	0.37	44%	0.46	62%
COPD Readmission (R = 0.7 with 537 cases)		0%		2%		9%
* Reliability of measure of hospital of median case size **Proportion of hospitals with case size large enough that R ≥ 0.4						

This data illustrates that both readmission measures fail to reach the industry standard of R = 0.75. KNG recommends that a minimum of 121 cases are needed for the pneumonia measure and 154 cases are need for the COPD measure in order to achieve R = 0.4. The current minimum threshold for the Yale readmissions measure is 25 cases—a major difference.

Pneumonia and COPD readmission measures

The *Affordable Care Act* calls for these readmission measures to recognize planned cases and unrelated admissions; however these measures do not. Therefore, they may be erroneously counting certain admissions and readmissions. Because this readmission measure is currently publicly reported and will be used to change reimbursement for hospitals in the near future, this omission must be rectified immediately. We urge the steering committee to take this into consideration and we ask the steering committee to query the measure developer on why this change has not been made to the measure.

Harmonization. Though the pneumonia and COPD readmission measures do not properly account for unrelated readmissions, we note that another NQF-endorsed measure (30-day all-cause all-condition risk standardized measure) does remove some planned readmissions. Therefore, pneumonia and COPD measures are not harmonized with the all-condition readmission measure. The all-condition readmission measure excludes patients undergoing medical treatment for their cancer as well as 27 other categories of procedures that are considered unplanned. **We urge the steering committee to require the measure developer to harmonize these methodologies by also excluding these planned readmissions from the pneumonia and COPD readmission measures**.

COPD mortality measure
Based on comments in the "Evidence" section of the steering committee's evaluation for this measure, it appears that the goal of this measure is to encourage hospitals to follow guidelines for COPD exacerbation management. However, the measure developer could create a more direct, process of care measure that evaluates whether the hospital followed such guidelines, or that measures their coordination of care, rather than creating a measure impacted by multiple outside factors.

The exclusion of FFS Medicare patients enrolled in Hospice is a good attempt to delineate between patients going through aggressive treatment and those who have chosen to enter palliative care programs. It is not clear whether there are Medicare patients who are not part of this exclusion. In other words, why does the measure exclude FFS Medicare patients enrolled in Hospice as opposed to all Medicare patients enrolled in Hospice? In addition, this exclusion does not completely remove from the measure population all of those patients who are terminally ill, because Hospice programs may be full. It also does not appear to remove sicker patients who have signed a DNR measure. In short, the risk adjustment and exclusions do not seem to identify and address the sickest patients.

The exclusions for this measure lack consistency with the exclusions for the 30-day all-cause risk-standardized mortality rate for pneumonia. The PN measure includes an exclusion for patients discharged alive on the day of admission or the following day who did not get transferred, because it is unlikely the patient had a significant pneumonia diagnosis. Why would the same kind of exclusion, such as lack of a significant COPD episode, not be part of the 30-day COPD measure?

The description of the adjustment/stratification for this measure included in the draft report also notes that "the RSMR is calculated as the ratio of the number of "predicted" to the number of "expected" deaths, multiplied by the national unadjusted mortality rate." Should this be the national unadjusted mortality rate for COPD?

References
A
http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/hospital-value-based-purchasing/index.html?redirect=/hospital-value-based-purchasing
http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1140537255912

B
http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier2&cid=1140537255912

C
KNG used 2009 100% Medicare inpatient claims data to identify Medicare beneficiaries admitted to short-term acute care hospitals with a principal diagnoses of one of the 3 initial conditions that will be included in the program (acute myocardial infarction, pneumonia and heart failure). To develop the analytic sample, we applied inclusion and exclusion criteria

consistent with the Medicare readmission measures endorsed by the National Quality Forum and used by CMS. Demographic and other characteristics of Medicare beneficiaries, such as age, sex, race, and dual eligible status were obtained from the 2009 Medicare denominator file. We were unable to use CMS's risk-adjustment methodology because 100% Medicare physician claims were not available to us. Instead, we used the Elixhauser comorbidity index for risk adjustment. The Elixhauser comorbidity measure is widely used in the literature as a risk-adjustment method for its proven predictive power of inpatient mortality. Following the approach used by CMS, we computed risk-standardized readmission rates (RSRRs) for each hospital and condition using a hierarchical regression model (HRM), which included hospital-level random effects.