TO: Consensus Standards Approval Committee (CSAC)

FR: Reva Winkler, Kathryn Streeter and Jessica Weber

RE: Pulmonary and Critical Care Follow-up

DA: January 14, 2013

The CSAC will consider the Steering Committee's recommendations for two remaining measures within the *Pulmonary and Critical Care Endorsement Maintenance Project* during its February 12th conference call.

This memo includes summary information on the measures, and themes identified from and responses to the public and member comments.

This project followed the National Quality Forum's (NQF) version 1.9 of the Consensus Development Process (CDP). Due to low voter participation in the initial round of voting, the CSAC requested a second round of voting. NQF member voting on the two recommended measures will end on February 6, 2013.

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC may consider approval of two candidate consensus standards.

Pulmonary and Critical Care Measure Recommended for Endorsement:

- ***0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations***
- ***1891 Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations***

Pulmonary and Critical Care Measure Not Recommended:

- ***0356: PN3a--Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival***

BACKGROUND
These three measures were initially considered with all measures in the Pulmonary and Critical Care Endorsement Maintenance project and were recommended for endorsement. Following the initial comment period in June 2012, the two readmission measures were updated by the developer (CMS/Yale) in accordance with planned modifications as well as in response to comments received. Changes to these measures primarily focused on addressing harmonization and incorporating a planned readmissions algorithm, which was strongly supported by the Steering Committee. As a result of these updates, the Steering Committee conducted a supplemental review of the measures in October 2012. The revised measures were recommended for endorsement and underwent a second commenting period in November 2012, since material changes were made to the specifications.

Additionally, measure 0356 is included in the addendum due to comments received during the initial commenting period, which noted a lack of evidence linking the measure to a direct improvement in patient outcomes. After the Steering Committee's review of these comments, the measure was reconsidered. The Committee re-voted the measure and did not recommend for endorsement.

DRAFT REPORT

The Pulmonary and Critical Care Endorsement Maintenance: Report Addendum presents the results of the evaluation of three measures considered under the CDP. Two measures are recommended for endorsement as voluntary consensus standards suitable for accountability and quality improvement and one was not recommended. The measures were evaluated against the 2011 version of the measure evaluation criteria.

COMMENTS AND THEIR DISPOSITION

First comment period

Comment Themes and Committee Responses

The Steering Committee reviewed and responded to all comments received. Comments were also forwarded to the developers, who were invited to respond. During the first comment period, two main themes were identified pertaining to the three measures.

Theme 1 - Outcome measures

In a letter with multiple comments from the American Hospital Association addressed several issues pertaining to the readmission measures from CMS/Yale:

0506 Thirty-day all-cause risk standardized readmission rate following pneumonia hospitalizations

1891 Thirty-day all-cause risk standardized readmission rate following COPD hospitalizations

The developer responded to the following comments:

- Failure to adjust for factors beyond the hospital's control such as patient characteristics, extreme circumstances, patient compliance and quality of post-acute care.

  Developer response: "Consistent with NQF guidelines, the measures do not adjust for socioeconomic status (SES) or race. Any association between SES/race and health outcomes can be due, in part, to differences in the quality of health care received by groups of patients with varying SES or race. Risk-adjusting for patient SES/race would suggest that hospitals with low SES/minority patients are held to different standards for patient outcomes than hospitals treating higher SES patient populations. It could also mask important disparities and minimize incentives to improve outcomes for vulnerable populations. Again, the intention is for the measures to adjust for patient demographic and clinical characteristics while illuminating important quality differences."

"Although patients and other providers share responsibility for improving care outcomes, CMS expects hospitals to work to improve patient compliance and to arrange quality post acute care, and CMS believes it is therefore appropriate to hold hospitals accountable for the short-term outcomes of mortality and readmission without accounting directly for these factors. CMS is also continuing to develop quality measures, including readmission measures, for post-acute care providers."

- Reliability – A recent CMS study required by the Accountable Care Act "shows the claims-based measures are unreliable." Additional reliability analyses are provided by KNG showing similar results.

  Developer response: "[Reliability] is often a confusing issue, because there are many different meanings and definitions of "reliability"; moreover, some reliability metrics refer to "intra-class correlation" (ICC), and there are several different metrics with this name as well. The AHA remarks mention three different reliability statistics, not all of which pertain to our measure." A detailed discussion of reliability from CMS/Yale is posted on the project web page.

- Harmonization with the recently endorsed measure *1789: Hospital-wide all-cause readmission measure* to exclude planned readmissions; harmonization of exclusions in the COPD measures compared to the pneumonia measures that include exclusions for discharged alive on day 0 or 1.

  Developer response: "CMS recently developed an algorithm for identifying planned readmissions that is used in the hospital-wide measure and plans to adapt it for the COPD and pneumonia readmission measures." CMS/Yale advised the Committee that the algorithm would be available several weeks after the initial comment period.

ACTION TAKEN:

- The Committee reviewed the AHA comments and the extensive responses provided by the developer. The Committee indicated that the responses adequately addressed the issues raised by AHA.
- The Committee supports the plan of Yale/CMS to include the algorithm for planned readmissions in measures 0506 and 1891 and looks forward to reviewing the additional information in the future.

Theme 2- Lack of Support for Recommended Measures

Comments indicated lack of support for several recommended measures:

- *0356: PN3a--Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival*

Comments from APIC, SCCM and ACEP indicated lack of support for this measure, citing lack of any high level evidence that this process measure is directly linked to improved patient outcomes for pneumonia patients; the measure does not state that blood cultures should be obtained before the initiation of

treatment; and the measure may create an unnecessary distraction from the delivery of more important care that needs to be delivered in the ED or ICU settings for not supporting this measure.

ACTION TAKEN:

> After reviewing the comments and additional discussion with the measure developer, the Committee decided to reconsider their recommendation of the measure. The Committee reviewed the evidence that the process will improve outcomes again. On re-vote, the Committee did not recommend the measure for endorsement.

Second comment period

During the second commenting period, NQF received 17 comments from six NQF member organizations and individuals pertaining to the three measures under consideration in the addendum.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Steering Committee and measure developers, is posted to the Pulmonary and Critical Care project page under the Public and Member Comment section.

Comment Themes and Committee Responses

The Steering Committee reviewed and responded to all comments received. Comments were also forwarded to the developers, who were invited to respond.

Theme 1 - Response to the concerns voiced during the initial project comment period in June 2012

A commenter commended the NQF, the Steering Committee and the measure developer (CMS/Yale) for their consideration of the concerns voiced by the American Hospital Association and other stakeholders during the initial project comment period in June 2012.

Theme 2 - Support the planned readmission algorithm

Several commenters expressed support for the revisions that includes a new algorithm to exclude planned readmissions that is harmonized with three other NQF-endorsed readmission measures from CMS/Yale. Comments note, however, that the algorithm identifies a very small number of planned readmissions. The commenter suggested that there is an opportunity to use the field experience going forward to determine whether additional changes are warranted and request that the developer provide an assessment at the annual update. Another commenter recommended that the exclusion/inclusion selection criteria methodology be improved with frequent reviews and revisions.

Theme 3 – Concerns with the measures

Commenters voiced various concerns with the measures:

- Excluding patients with medical conditions or comorbidities that often require multiple episodes of care;
- Concerns about reliability;

- Distinguishing between related and unrelated admissions;
- Accounting for socioeconomic factors;
- Including ages 40 years and older for the COPD measure; and
- Using the hierarchical modeling in the risk adjustment methodology

Developer response: Refer the responses from the first comment period.

ACTION TAKEN

- The Committee was satisfied with the developer's response, and reaffirmed its recommendations of measures 0506 and 1891 for endorsement. They also requested the draft report reflect the Committee's considerable discussion regarding the measure's ability to distinguish between related and unrelated admissions and socioeconomic factors.

NQF MEMBER VOTING

Due to low voter participation in the initial round of voting, the CSAC requested a second round of voting. The results rom the second round of voting will be provided before the February call.

REMOVE ENDORSEMENT OF MEASURE

One measure previously endorsed by NQF was not recommended for continued endorsement:

Measure	**Description**	**Reason for removal of endorsement**
0356: PN3a--Blood Cultures Performed Within 24 Hours Prior to or 24 Hours After Hospital Arrival for Patients Who Were Transferred or Admitted to the ICU Within 24 Hours of Hospital Arrival	Percent of pneumonia patients, age 18 years or older, transferred or admitted to the ICU within 24 hours of hospital arrival who had blood cultures performed within 24 hours prior to or 24 hours after arrival at the hospital.	The Steering Committee did not recommend due to not meeting the evidence criterion.

NATIONAL QUALITY FORUM

Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

1891 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization

Status: New Submission

Description: The measure estimates a hospital-level risk-standardized readmission rate (RSRR), defined as readmission for any cause within 30 days after the date of discharge of the index admission, for patients 40 and older discharged from the hospital with either a principal diagnosis of COPD or a principal diagnosis of respiratory failure with a secondary diagnosis of acute exacerbation of COPD.

Numerator Statement: The outcome for this measure is 30-day all-cause readmission. We define all-cause readmission as an inpatient admissions for any cause within 30 days after the date of discharge from the index admission.for patients 40 and older discharged from the hospital with either a principal diagnosis of COPD or a principal diagnosis of respiratory failure with a secondary diagnosis of acute exacerbation of COPD. If a patient has one or more admissions (for any reason) within 30 days after discharge from the index admission, only one is counted as a readmission. For the detailed definition of planned readmissions, please refer to the attached report, Respecifying the Hospital 30-Day Pneumonia and 30-Day Chronic Obstructive Pulmonary Disease Readmission Measures by adding a Planned Readmission Algorithm.

Denominator Statement: This claims-based measure can be used in either of two patient cohorts: (1) patients aged 65 years or older or (2) patients aged 40 years or older. We have explicitly tested the measure in both age groups.

The cohort includes admissions for patients discharged from the hospital with either a principal diagnosis of COPD (see codes below) OR a principal diagnosis of respiratory failure (see codes below) WITH a secondary discharge diagnosis of acute exacerbation of COPD (see codes below) and with a complete claims history for the 12 months prior to admission.

Exclusions: An index admission is any eligible admission to an acute care hospital assessed in the measure for the outcome (readmitted within 30 days of the date of discharge from the initial admission).

The measure excludes admissions for patients:

• with an in hospital death (because they are not eligible for readmission).

• transferred to another acute care facility (We assign the outcome for the acute episode of care to the hospital that discharges the patient to the non-acute care setting because the discharging hospital initiates the discharge and the transition to the outpatient setting. Therefore, the last admission in the acute care setting for the episode of care is eligible to be an index admission in the measure. The prior admissions in the same acute episode are excluded from the measure.)

• who were discharged alive and against medical advice (AMA) (because providers did not have the opportunity to deliver full care and prepare the patient for discharge).

• without at least 30 days post-discharge claims data (because the 30-day readmission outcome cannot be assessed in this group).

Additionally, admissions that occur within 30 days of the discharge date of an earlier index admission are not themselves considered to be index admissions. Any COPD admission can only be an index admission or a readmission, but not both.

Of note, a patient may satisfy multiple exclusion criteria.

Adjustment/Stratification: Statistical risk model Our approach to risk adjustment is tailored to and appropriate for a publicly reported outcome measure, as articulated in the American Heart Association (AHA) Scientific Statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes”1.

1891 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization

The measure employs a hierarchical logistic regression model to create a hospital-level 30-day RSRR. This approach to modeling appropriately accounts for the structure of the data (patients clustered within hospitals), the underlying risk due to patients' comorbidities, and sample size at a given hospital when estimating hospital readmission rates. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals.2 At the patient level, the model adjusts the log-odds of readmission within 30 days of discharge for age and selected clinical covariates. The second level models hospital-specific intercepts as arising from a normal distribution. The hospital-specific intercepts represent the hospital contribution to the risk of readmission, after accounting for patient risk and sample size, and can be inferred as a measure of quality. The hospital-specific intercepts are given a distribution in order to account for the clustering (non-independence) of patients within the same hospital. If there were no differences among hospitals, then after adjusting for patient risk, the hospital intercepts should be identical across all hospitals.

The RSRR is calculated as the ratio of the number of "predicted" to the number of "expected" readmissions, multiplied by the national unadjusted readmission rate. For each hospital, the numerator of the ratio ("predicted") is the number of readmissions within 30 days predicted on the basis of the hospital's performance with its observed case mix, and the denominator ("expected") is the number of readmissions expected on the basis of the nation's performance with that hospital's case mix. This approach is analogous to a ratio of "observed" to "expected" used in other types of statistical analyses. It conceptually allows for a comparison of a particular hospital's performance given its case-mix to an average hospital's performance with the same case-mix. Thus, a lower ratio indicates lower-than-expected readmission or better quality and a higher ratio indicates higher-than-expected readmission or worse quality.

The predicted hospital outcome (the numerator) is the sum of predicted probabilities of readmission for all patients at a particular hospital. The predicted probability of each patient in that hospital is calculated using the hospital-specific intercept and patient risk factors. The expected number of readmissions (the denominator) is the sum of expected probabilities of readmission for all patients at a hospital. The expected probability of each patient in a hospital is calculated using a common intercept and patient risk factors.

Candidate and Final Risk-adjustment Variables: The measure was developed using Medicare FFS claims data. Candidate variables were patient-level risk-adjustors that were expected to be predictive of readmission, based on empirical analysis, prior literature, and clinical judgment, including age and indicators of comorbidity and disease severity. For each patient, covariates are obtained from Medicare claims extending 12 months prior to and including the index admission. The model adjusts for case mix differences based on the clinical status of patients at the time of admission. We used condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis codes, and combinations of CCs as candidate variables. A file which contains a list of the ICD-9-CM codes and their groupings into CCs is available on www.qualitynet.org (http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1182785083979). We did not risk-adjust for CCs that were possible adverse events of care and that were only recorded in the index admission. Only comorbidities that conveyed information about the patient at that time or in the 12 months prior, and not complications that arose during the course of the hospitalization were included in the risk-adjustment.

References:

1. Krumholz HM, Brindis RG, Brush JE, et al. 2006. Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. Circulation 113: 456-462.

2. Normand S-LT, Shahian DM. 2007. Statistical and Clinical Aspects of Hospital Outcomes Profiling. Stat Sci 22 (2): 206-226.

Frequencies and odds ratios for the model development sample (2008 Medicare FFS patients aged 65 and older; n=170,480 admissions) are presented below.

Table 1: Final set of risk-adjustment variables:

NATIONAL QUALITY FORUM

1891 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization

Variable//Frequency (%)//Odds Ratio (95% confidence interval)
Demographic
• Age-65 (years above 65, continuous) for 65 and over cohorts/Frequency = -/OR (95% CI)=1.00 (1.00-1.00); (this variable is Age (years, continuous) for 18 and over cohorts)
Cardiovascular/Respiratory
• Sleep Apnea (ICD-9 CM diagnosis codes: 327.20, 327.21, 327.23, 327.27, 327.29, 780.51, 780.53, 780.57) / Frequency=10.46% / OR (95% CI)=1.00 (0.96-1.03)
• History of mechanical ventilation (ICD-9 procedure codes: 93.90, 96.70, 96.71, 96.72)/ Frequency=7.33/ OR (95% CI)=1.13 (1.08-1.18)
• Respirator dependence/respiratory failure (CC 77-78)/ Frequency=1.38/ OR (95% CI)=1.12 (1.03-1.23)
• Cardio-respiratory failure and shock (CC 79)/ Frequency=29.84/ OR (95% CI)=1.21 (1.18-1.24)
• Congestive heart failure (CC 80)/ Frequency=43.86/ OR (95% CI)=1.21 (1.18-1.24)
• Chronic atherosclerosis (CC 83-84)/ Frequency=51.57/ OR (95% CI)=1.11 (1.08-1.13)
• Arrhythmias (CC 92-93)/ Frequency=37.2/ OR (95% CI)=1.17 (1.12-1.22)
• Vascular or circulatory disease (CC 104-106)/ Frequency=38.2/ OR (95% CI)=1.09 (1.05-1.14)
• Arrhythmias (CC 92-93)/ Frequency=38.48/ OR (95% CI)=1.14 (1.11-1.17)
• Other and Unspecified Heart Disease (CC 94)/ Frequency=19.45/ OR (95% CI)=1.08 (1.05-1.11)
• Vascular or Circulatory Disease (CC 104-106)/ Frequency=39.42/ OR (95% CI)=1.09 (1.06-1.11)
• Fibrosis of lung and other chronic lung disorder (CC 109)/ Frequency=18.12/ OR (95% CI)=1.09 (1.06-1.12)
• Pneumonia (CC 111-113)/ Frequency=51.51/ OR (95% CI)=1.10 (1.07-1.13)
Other Comorbid Conditions
• History of Infection (CC 1, 3-6)/ Frequency=32.16/ OR (95% CI)=1.08 (1.05-1.11)
• Metastatic cancer and acute leukemia (CC 7)/ Frequency=2.64/ OR (95% CI)=1.24 (1.15-1.33)
• Lung, upper digestive tract, and other severe cancers (CC 8)/ Frequency=5.91/ OR (95% CI)=1.19 (1.13-1.25)
• Lymphatic, head and neck, brain, and other major cancers; breast, prostate, colorectal and other cancers and tumors; other respiratory and heart neoplasms (CC 9-11)/ Frequency=13.88/ OR (95% CI)=1.04 (1.01-1.08)
• Other digestive and urinary neoplasms (CC 12)/ Frequency=7.06/ OR (95% CI)=0.96 (0.92-1.01)
• Diabetes and DM complications (CC 15-20, 119-120)/ Frequency=39.15/ OR (95% CI)=1.08 (1.05-1.11)
• Protein-calorie malnutrition (CC 21)/ Frequency=7.57/ OR (95% CI)=1.14 (1.09-1.19)
• Disorders of Fluid/Electrolyte/Acid-Base (CC 22-23)/ Frequency=34.57/ OR (95% CI)=1.17 (1.14-1.20)
• Other Endocrine/Metabolic/Nutritional Disorders (CC 24)/ Frequency=68.61/ OR (95% CI)=0.91 (0.89-0.94)
• Pancreatic Disease (CC 32)/ Frequency=4.85/ OR (95% CI)=1.12 (1.06-1.17)
• Peptic Ulcer, Hemorrhage, Other Specified Gastrointestinal Disorders (CC 34)/ Frequency=12.58/ OR (95% CI)=1.07 (1.03-1.11)
• Other Gastrointestinal Disorders (CC 36)/ Frequency=58.29/ OR (95% CI)=1.04 (1.02-1.07)
• Severe Hematological Disorders (CC44)/ Frequency=2.07 /OR (95% CI)=1.12 (1.04-1.20)
• Iron Deficiency and Other/Unspecified Anemias and Blood Disease (CC 47)/ Frequency=42.09/ OR (95% CI)=1.13 (1.10-1.16)
• Dementia and senility (CC 49-50)/ Frequency=17.07 /OR (95% CI)=1.00 (0.97-1.04)
• Drug/Alcohol Induced Dependence/Psychosis (CC 51-52)/ Frequency=3.67/ OR (95% CI)=1.15 (1.09-1.22)
• Major Psych Disorders (CC 54-56)/ Frequency=10.79/ OR (95% CI)=1.08 (1.04-1.12)
• Depression (CC 58)/ Frequency=19.63/ OR (95% CI)=1.06 (1.03-1.09)
• Anxiety Disorders (CC 59)/ Frequency=3.27/ OR (95% CI)=1.15 (1.08-1.22)
• Other Psychiatric Disorders (CC 60)/ Frequency=18.37/ OR (95% CI)=1.11 (1.08-1.15)
• Quadriplegia, paraplegia, functional disability (CC 67-69, 100-102, 177-178)/ Frequency=5.02/ OR (95% CI)=1.08 (1.02-1.13)
• Polyneuropathy (CC 71)/ Frequency=7.91/ OR (95% CI)=1.11 (1.06-1.16)
• Acute Coronary Syndrome (CC 81-82)/ Frequency=9.54/ OR (95% CI)=1.08 (1.04-1.12)

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• Hypertensive Heart and Renal Disease or Encephalopathy (CC 89)/ Frequency=13.20/ OR (95% CI)=1.13 (1.09-1.17)
• Stroke (CC 95-96)/ Frequency=6.84/ OR (95% CI)=1.04 (1.00-1.09)
• Renal Failure (CC 131)/ Frequency=18.61/ OR (95% CI)=1.10 (1.06-1.14)
• Decubitus ulcer or chronic skin ulcer (CC 148-149)/ Frequency=7.43/ OR (95% CI)=1.03 (0.99-1.08)
• Cellulitis, Local Skin Infection (CC 152)/ Frequency=12.50/ OR (95% CI)=1.07 (1.03-1.11)
• Vertebral Fractures (CC 157)/ Frequency=5.24/ OR (95% CI)=1.14 (1.08 -1.19)
ICD-10-CM codes for model variables (for those variables defined by ICD-9 CM codes rather than CCs)
Mechanical Ventilation
• 5A09357 Assistance with Respiratory Ventilation, Less than 24 Consecutive Hours, Continuous Positive Airway Pressure
• 5A09457 Assistance with Respiratory Ventilation, 24-96 Consecutive Hours, Continuous Positive Airway Pressure
• 5A09557 Assistance with Respiratory Ventilation, Greater than 96 Consecutive Hours, Continuous Positive Airway Pressure
• 5A1935Z Respiratory Ventilation, Less than 24 Consecutive Hours
• 5A1945Z Respiratory Ventilation, 24-96 Consecutive Hours
•5A1955Z Respiratory Ventilation, Greater than 96 Consecutive Hours
Sleep Apnea
• G4730 Sleep apnea, unspecified
• G4731 Primary central sleep apnea
• G4733 Obstructive sleep apnea (adult) (pediatric)
• G4737 Central sleep apnea in conditions classified elsewhere
• G4739 Other sleep apnea Results of this measure will not be stratified.

Level of Analysis: Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services (CMS) **Other organizations:** MPR: Mathematica Policy Research; RTI: Research Triangle Institute

Steering Committee Evaluations

Importance to Measure and Report (***based on decision logic***)**: PASSED all three sub-criteria**

1a. Impact: H-17; M-1; L-0; I-0; **1b. Performance Gap: H-15; M-3; L-0; I-0**

Rationale:

- COPD is a leading cause of readmissions to the hospital.
- 1a: The developer presented data demonstrating significant poor outcomes (readmissions) and high cost.
- 1b: The submission describes the 30-day readmission rate among patients hospitalized for COPD is 22.6%, accounting for 4% of all 30-day readmissions. Analysis of Medicare FFS patients, crude readmission rates of a national sample of 176,481 patients across 4,547 hospitals demonstrates that hospital readmission rates for COPD patients are generally high, at a mean of 21.8%, and that there is a large amount of variation in outcomes, with the rates ranging from 10.8-32.6% (5th and 95th percentiles respectively).

1c. Evidence (*based on decision logic*): **Y-18; N-1; I-0**

Rationale:

- This is an outcome measure.

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- Strong evidence base exists for interventions to improve outcomes such as readmission rates.

2. Scientific Acceptability of Measure Properties (*based on decision logic*): PASSED reliability and validity

2a. Reliability: H-15; M-4; L-0; I-0; 2b. Validity: H-3; M-10; L-5; I-1

Rationale:

- 2a: Measure specifications are clear and consistent and can be reliably measured.
    - 30 days begins at discharge from acute care regardless of whether patient goes to a LTAC, SNF or rehabilitation facility.
- 2b: Risk adjustment methodology is robust.
    - Individual risk factors should include rate of previous exacerbations and active smoking status if available. Institutional risk "factors" should include regional long term particle pollution levels and if individual active smoking rates are not available, regional smoking rates. All are known to contribute to exacrbations of COPD.
    - Concerns about risk adjustment for patients who had exacerbations and were ventilated but not for patients with previous admissions with exacerbations.
    - The numbers of patients with COPD diagnosis between 18-40 years is very small.
    - Multiple readmissions within the 30-day window only count once.
    - A patient may be counted more than once if they have multiple admissions during the year.

3. Usability: H-7; M-11; L-1; I-0

(*Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)*

Rationale:

- 3a-3b: Similar measures have been used for other clinical conditions (e.g., AMI, HF, PN) and have been demonstrated to support both public reporting and quality improvement
- Measure was recently tested and expanded to include those beyond the Medicare population (18 years and above).
- CMS is monitoring observation stays to assess whether use of the readmission measure would incentivize hospitals potentially to increase their use of observation stays in lieu of admitting patients who come back to the hospital within the 30-day time frame.
- The measure publicly reported by CMS rolls up 3 years of data so the results are not timely which hampers quality improvement activities.

4. Feasibility: H-14; M-5; L-0; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- The measure is based on adminstrative data.

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Steering Committee Assessment of Criteria Met/Suitable for Endorsement: Y-17; N-2

Rationale:

- Outcome measure.
- Variation in outcomes demonstrate opportunity for improvement.
- Unknown impact of local air quality should be explored for possible impact on the measure results.

Additional Comments/Questions:

- The Committee requested a commitment from CMS to explore the possible effect of differences in air quality at hospital locations on the results of the measures for 30-day Mortality and 30-day Readmissions for COPD.
- The Committee requested additional information about the 18-40 year population.

Measure Developer Response:

CMS appreciates the Committee members' suggestion that we consider adjusting the COPD measures for ambient particulate levels using monitoring data available from the US Environmental Protection Agency (EPA). We asked the measure developer, YNHHSC/CORE, to conduct a brief literature review and consult with 2-3 experts to explore this suggestion. YNHHSC/CORE found that, as noted by the Committee, the literature suggests that ambient levels of particulate matter affect short-term mortality and admission rates for COPD (and for other cardiovascular and respiratory conditions). EPA considered these effects in its most recent revision to its health-based national ambient air quality standard for particulates. Although important from a public health standpoint, these increases are relatively small. YNHHSC/CORE did not find any studies of the effect of ambient particulates on mortality and readmission rates among hospitalized patients for COPD.

The purpose of risk adjustment is to account for differences across hospitals in factors unrelated to quality, such as patient comorbidities, that may affect the outcome of mortality and readmission. It is important to risk adjust for factors that could bias the measure results (e.g. could favor hospitals in low pollution areas). Adjusting for particulates would make sense if it were technically feasible and if it would improve the model by reducing or eliminating a potential bias.

Based on its review, YNHHSC/CORE does not recommend adding a PM variable as it is unlikely to affect hospital-level risk-standardized rates. The studies to date focus on the general non-hospitalized population, and it is not clear how they apply to the patients in our models – that is, patients hospitalized with an acute exacerbation of COPD. YNHHSC/CORE reported that the experts felt the effect of adjusting for PM would likely be small or negligible given that the model applies to patients already hospitalized for COPD. Second, there are feasibility issues. Modeling the effect appropriately would be complex. YNHHSC/CORE's preliminary review of the issues suggests it would be inappropriate to use ambient air quality levels as a risk adjuster without also adjusting for other factors that affect the strength and direction of the potential association between particulate levels and the outcomes, including temperature, humidity, seasonal variation, and city-level factors such as smoking and air conditioning use rates. Given these challenges, and our expectation that building particulate levels into the model is not likely to significantly improve the models' performance even with the best methods, CMS does not plan to pursue adding air pollution variables to the models at this time.

Public & Member Comment

Comments included:

- Concerns about the reliably and validly of the ICD-9-CM coding used to identify the intended target population.

  Developer response: In the development of the COPD measures we followed a careful process aimed

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at selecting a cohort that is both clinically coherent and comprehensive. The cohort codes were informed by a thorough literature review and a review of codes used for other COPD measures. They have also been reviewed by both a working group of experts knowledgeable about ICD-9 coding for the COPD population and a national Technical Expert Panel. This group, for example, made the decision to include patients with primary discharge diagnosis codes of respiratory failure and secondary codes for COPD in order to increase the sensitivity of case selection. Finally, a study by Brian Stein et al, published in Chest 2012 suggests that a set of ICD-9 codes similar to the ones we used to define the cohort has high positive predictive value. The commenter also refers to the medical record validation process used in prior CMS measures (e.g. pneumonia mortality and readmission). Previously, CMS has undergone medical record validation to confirm the adequacy of administrative codes for risk-adjustment but not to assess cohort selection. The selection of the appropriate codes for identifying the cohort is based on face validity and review of experts with knowledge of coding practices. CMS has a process for yearly maintenance of the measures, at which time the cohort codes will be reassessed to evaluate any need for changes or updates.

- Suggest measure 1891 only be reported as a paired measure along with 1893 in order to more accurately reflect both outcomes of interest, the overall quality of care provided, and to enhance usability.

  Developer response: CMS agrees that they are complementary and that reporting both measures provides a fuller picture of care; however, CMS has submitted the measures to NQF as independent measures. CMS will consider this preference in its approach to implementation.

- AHA submitted a letter which is posted on the NQF project page outlining concerns with the following issues:
  - Failure to adjust for factors beyond the hospital's control such as patient characteristics, extreme circumstances, patient compliance and quality of post-acute care.
  - Reliability – A recent CMS study required by the Accountable Care Act "shows the claims-based measures are unreliable." Additional reliability analyses are provided by KNG showing similar results.
  - Harmonization with the recently endorsed measure 1789: Hospital-wide all-cause readmission measure to exclude planned readmissions; harmonization of exclusions in the COPD measures compared to the pneumonia measures that include exclusions for discharged alive on day 0 or 1.
  - Exclusions for all Medicare patients in Hospice rather than just FFS Medicare patients enrolled in hospice.

  Developer response: Detailed responses to the AHA comments from the developer are posted on the NQF project page addressing all four issues. CMS will provide additional information on including exclusions for planned readmissions by July 11 for the Committee to consider.

- CMS/Yale advised the Committee that, in response by a recommendation from this Committee, the age range for measures 1891 and 1893 was changed to 40 years and above. The developers note that COPD is rare in the less than 40 age group (1.5% of patients in our 2006 California all payer dataset), and a diagnosis at younger ages is likely to represent the misclassification of patients with asthma or other pulmonary conditions. This approach is commonly used in the research literature.

Steering Commitee response:

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- The Committee agrees with the change in age to 40 and above for measures 1891 and 1893.
- The Committee reviewed the extensive responses provided by the developer. The Committee indicated that the responses adequately addressed the issues raised by AHA.
- The Committee supports the plan of Yale/CMS to include the algorithm for planned readmissions in measures 0506 and 1891 and looks forward to reviewing the additional data in the next few weeks.
- In response to the comment, CMS/Yale requested additional time to work on harmonization of exclusions using a new algorithm for planned readmission for the all readmission measures, including pneumonia and COPD.

Additional Steering Committee Review – October 16, 2012

- The Committee reviewed the additional information on the algorithm for planned readmissions provided by Yale CORE.
- The Committee agreed that the list of planned readmission exclusions were reasonable and noted the change in raw readmission rate was less than 1% and the minimal impact on the risk model.
- The Committee unanimously maintained their recommendation for endorsement.

Steering Committee Reassessment of Criteria Met/Suitable for Endorsement: Y-14; N-0

RECOMMEND FOR ENDORSEMENT

Additional Public and Member Comment:

- A commenter ecommended that measure description be corrected to state patients 40 years of age and older.

  NQF response: Previously, this measure was modified by the developer at the request of the Steering Committee to include ages 40 years and older. NQF staff will review all documents to ensure the change in included.

- Commenters voiced various concerns including: excluding patients with medical conditions or comorbidities that often require multiple episodes of care; concerns about reliability and potential unintended consequenses.

  Developer response: The measures address clinical differences in hospitals' case-mix through risk adjustment rather than through excluding patients from the measure as suggested by the commenter. The goal in developing outcomes measures is to create a clinically cohesive cohort that includes as many patients as possible admitted with the given condition. Greatly expanding our list of exclusions would result in a measure that was less useful and meaningful, because it would reflect the care of fewer patients and diverse clinical conditions. To fairly profile hospitals' performance, it is critical to place hospitals on a level playing field and account for their differences in the patients that present for care. This is accomplished through adequate risk-adjustment for patients' clinical presentation rather than exclusion of patients. In addition, the expanded planned readmission definitions for the measures will identify as planned and not count in the outcome readmissions for procedures for procedures, such as wound debridement, that represent routine care for patients with chronic conditions.

  We appreciate the points AHA raises about reliability. In a June 19, 2012 memo to NQF we responded to the KNH Health Consulting work in detail. We note that CMS uses 3 years of data to calculate the measure results for the Inpatient Quality Reporting and Hospital Readmission Reduction programs to increase the measures' reliability.

- A commenter voiced concern over the use of the hierarchical risk adjustment model in this and other,

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similar readmission measures. This method of risk adjustment drives the data toward the mean, and does not result in meaningful display of the variation in performance and/or quality.

NQF response: The issue of hierarchical modeling has been discussed numerous times by Steering Committees, CSAC and Board. Last year a report from the Presidents of the major statistical societies addressed these issues for CMS**.**

- Additional comments were received voicing concerns incuding: distinguishing between related and unrelated admissions; accounting for socioeconomic factors; and use of hierarchical modeling in the risk adjustment methodology. The commenter suggest that there is an opportunity to use the field experience going forward to determine whether additional changes are warranted and request that the developer provide an assessment at the annual update.

  Developer response: We agree that the field experience with the measures can be informed by the planned readmission algorithm. We made several revisions to the algorithm based on input from the national dry run of CMS's hospital-wide readmission measure. We will continue to evaluate potential additional changes identified by hospitals as the measures are tested and used in CMS programs.
- A commenter recommended that the exclusion/inclusion selection criteria methodology be improved with frequent reviews and revisions. Unplanned readmissions that are not related to the index admission should be excluded from this measure and the measure be controlled for socioeconomic status, nonreversible comorbidities, and circumstances outside of the control of the provider.

  Developer response: The readmission measure was developed to be an all-cause measure for several reasons. There are several reasons for using all cause readmission as the outcome. First, from the patient perspective, readmission from any cause is an adverse event. Second, although we would expect few hospitals to use gaming strategies, measures should not create incentives for them to do so.

  Third, it is often hard to exclude quality issues and accountability based on the documented cause of readmission. The measure does not adjust for patient characteristics such as socioeconomic status (SES). The association between SES and health outcomes can be due, in part, to the differences in the quality of health care. Risk-adjusting for patient characteristics such as SES would suggest that hospitals with high proportions of such patients are held to different standards for the risk of readmission than hospitals treating higher-SES patient populations. For example, if patients of low socioeconomic status have higher readmission rates, then adjusting for SES in the model will lower the risk-standardized rates for hospitals with a higher proportion of these patients relative to other hospitals with clinically similar patients and similar outcomes. CMS does not want to hold hospitals with different SES mixes to different standards. Adjusting for SES would also obscure differences that are important to identify if we want to reduce disparities where they do exist. Thus, the choice was to adjust only for clinical differences in the populations among hospitals. This is consistent with guidance from the National Quality Forum recommending against adjusting for patient characteristics such as socioeconomic status in outcomes measures.
- A commenter requested a formal evaluation of the qualifying readmissions in the first year of the Readmission Reduction Program to determine if there should be further modifications to the planned readmission methodology.

  Developer response: We appreciate the AAMC's request for a "formal review" of the planned readmission algorithm in the first year of the Readmission Reduction Program. We note that the algorithm has undergone four rounds of public comment, as well as structured input from surgical subspecialists, technical expert panels, NQF committees, and hospitals participating in a national dry run of the hospital-wide and hip and knee arthroplasty readmission measures. The developer and CMS welcome continued comments and suggestions on the components of the algorithm as the revised

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measures are used.

- General support of the measure.

Steering Committee Response: The Committee reviewed the comments and responses from developers and made no changes to their recommendations.

0506 Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following pneumonia hospitalization

Status: Maintenance, Original Endorsement: Oct 28, 2008

Description: The measure estimates a hospital-level risk-standardized readmission rate (RSRR) defined as readmission for any cause within 30 days of the discharge date for the index hospitalization for patients discharged from the hospital with a principal diagnosis of pneumonia. The target population is patients 18 and over. CMS annually reports the measure for patients who are 65 years or older and are either enrolled in fee-for-service (FFS) Medicare and hospitalized in non-federal hospitals or are hospitalized in Veterans Health Administration (VA) facilities.

Since NQF-endorsement, the measure has been tested and shown to perform well in an all-payer population aged 18 and older and has been re-specified for this broader age group. The full details of the all-payer analysis and testing are attached.

Numerator Statement: The outcome for this measure is 30 day all-cause readmission. We define all-cause readmission as an inpatient admission for any cause within 30 days from the date of discharge from the index pneumonia admission. If a patient has one or more admissions (for any reason) within 30 days of the date of discharge of the index admission, only one was counted as a readmission. For the detailed definition of planned readmissions, please refer to the attached report, Respecifying the Hospital 30-Day Pneumonia and 30-Day Chronic Obstructive Pulmonary Disease Readmission Measures by adding a Planned Readmission Algorithm.

The numerator of the risk-adjusted ratio is the predicted number of readmissions within 30 days given the hospital's performance with its observed case mix. The term "predicted" describes the numerator result, which is calculated using the hospital-specific intercept term. (See details below in the 2a1.13 Statistical risk model and variables.)

Denominator Statement: The cohort includes admissions for patients 18 and over hospitalized for pneumonia. The measure is currently publicly reported by CMS for patients 65 years and older who are either enrolled in Medicare FFS and admitted to non-federal hospitals, or admitted to VA hospitals.
The measure includes admissions for patients discharged from the hospital with a principal diagnosis of pneumonia and with a complete claims history for the 12 months prior to admission.

Exclusions: The measure excludes admissions for patients:

For all cohorts, the measure excludes admissions for patients:

- with an in-hospital death (because they are not eligible for readmission);
- transferred to another acute care hospital (because the readmission is attributed to the hospital that discharges the patient to a non-acute setting);
- discharged against medical advice (AMA) (because providers did not have the opportunity to deliver full care and prepare the patient for discharge);
- admitted with pneumonia within 30 days of discharge from a qualifying index admission (Admissions within 30 days of discharge of an index admission will be considered readmissions. No admission is counted as a readmission and an index admission. The next eligible admission after the 30-day time period following an index admission will be considered another index admission.)

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For Medicare FFS patients, the measure additionally excludes admissions for patients:

- without at least 30 days post-discharge enrollment in FFS Medicare (because the 30-day readmission outcome cannot be assessed in this group).

Adjustment/Stratification: Statistical risk model Our approach to risk adjustment is tailored to and appropriate for a publicly reported outcome measure, as articulated in the American Heart Association (AHA) Scientific Statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes" (Krumholz et. al., 2006).
The proposed measure employs a hierarchical logistic regression model to create a hospital level 30-day RSRR. In brief, the approach simultaneously models two levels (patient and hospital) to account for the variance in patient outcomes within and between hospitals (Normand & Shahian, 2007). At the patient level, each model adjusts the log-odds of readmission within 30-days of discharge for age and selected clinical covariates. The second level models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of readmission, after accounting for patient risk. See section 2a1.20. Calculation Algorithm/Measure Logic for more detail.
Candidate and Final Risk-adjustment Variables: Candidate variables were patient-level risk-adjustors that were expected to be predictive of readmission, based on empirical analysis, prior literature, and clinical judgment, including age and indicators of comorbidity and disease severity. For each patient, covariates are obtained from Medicare claims extending 12 months prior to and including the index admission. The model adjusts for case mix differences based on the clinical status of patients at the time of admission. We use condition categories (CCs), which are clinically meaningful groupings of more than 15,000 ICD-9-CM diagnosis codes. A file which contains a list of the ICD-9-CM codes and their groupings into CCs is available at http://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1182785083979. In addition, only comorbidities that convey information about the patient at admission or in the 12-months prior, and not complications that arise during the course of the hospitalization, are included in the risk-adjustment. Hence, we do not risk adjust for CCs that may represent adverse events of care and that are only recorded in the index admission.
The final set of risk-adjustment variables is:
Demographics
Age-65 (years above 65, continuous)
Male
Comorbidities
History of coronary artery bypass graft (CABG) surgery
History of infection (CC 1, 3-6)
Septicemia/shock (CC 2)
Metastatic cancer and acute leukemia (CC7)
Lung, upper digestive tract, and other severe cancers (CC8)
Lymphatic, head and neck, brain, and other major cancers; breast, prostate, colorectal and other cancers and tumors (CC 9-10)
Diabetes mellitus (DM) and DM complications (CC 15-20, 119-120)
Protein-calorie malnutrition (CC 21)
Disorders of fluid/electrolyte/acid-base (CC 22-23)
Other gastrointestinal disorders (CC 36)
Severe hematological disorders (CC 44)
Iron deficiency and other/unspecified anemias and blood disease (CC 47)
Dementia and senility (CC 49-50)
Drug/alcohol abuse/dependence/psychosis (CC 51-53)
Major psychiatric disorders (CC 54-56)
Other psychiatric disorders (CC 60)
Hemiplegia, paraplegia, paralysis, functional disability (CC67-69, 100-102, 177-178)

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Cardio-respiratory failure and shock (CC 79)
Congestive heart failure (CC 80)
Acute coronary syndrome (CC 81-82)
Chronic atherosclerosis (CC 83-84)
Valvular and rheumatic heart disease (CC 86)
Arrhythmias (CC 92-93)
Stroke (CC 95-96)
Vascular or circulatory disease (CC 104-106)
Chronic obstructive pulmonary disease (CC 108)
Fibrosis N/A

Level of Analysis: Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services **Other organizations:** MPR: Mathematica Policy Research; RTI-Research Triangle Institute

IMPLEMENTATION COMMENTS

- None of the ACCP QIC members use this measure at their institution and have never seen any data related to this measure. The QIC questions whether or not this measure sees widespread use.

Steering Committee Evaluations

Importance to Measure and Report (***based on decision logic***)**: Passed all three subcriteria**

1a. Impact: H-19; M-0; L-0; I-0; **1b. Performance Gap: H-13; M-5; L-0; I-1**

Rationale:

- Clear measure of quaity and companion to measure 0458 30-day mortality rate - both are needed.
- Current readmission rate is 18.2% for Medicare patients.

1c. Evidence (*based on decision logic*): **Y-19; N-0; I-0**

Rationale:

- Need with 0458 for optimal quality assessment.
- This is an outcome measure.

2. Scientific Acceptability of Measure Properties (***based on decision logic***)**: Passed reliability and validity.**

2a. Reliability: H-14; M-5; L-0; I-0; 2b. Validity: H-11; M-7; L-0; I-1

Rationale:

- Extensive risk-adjustment with 12 month look-back for risk factors.
- Newly tested risk model to include all payer data is appropriate, reliable, and valid for use for all patients admitted with pneumonia.
- Standardization of the age to 18 years and older aligns with most other adult measures.
- For younger patients a readmission is less likely to be related to the pneumonia admission, except for cystic fibrosis patients, but the numbers will be rare and random.
    - The developer noted that the measure performs better in the younger age group perhaps due to fewer comorbidities.
- CMS is now tracking patients who go in to observation and are not formally admitted to see if this impacts the measure. Data will be provided when made publicly available.

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3. Usability: H-9; M-6; L-3; I-2

(*Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)*

Rationale:

- This measure is publicly reported on Hospital Compare.

4. Feasibility: H-17; M-2; L-1; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c.Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale:

- Uses administrative data.

Steering Committee Assessment of Criteria Met/Suitable for Endorsement: Y-18; N-2

Rationale:

- Publicly reported outcome measure that has been in use for several years.
- The measure has been expanded beyond the Medicare population.

Public & Member Comment

Comments included:

- Concerns that the claims-based definition of pneumonia lacks sufficient validity and requests that the definition be updated to reflect coding trends, noting that this measure does not include patients with a primary diagnosis of sepsis or respiratory failure and a secondary diagnosis of pneumonia. A recent published study shows that hospital admissions with a primary diagnosis of pneumonia are declining over time, while at the same time admissions with a primary diagnosis of sepsis or respiratory failure and a secondary diagnosis of pneumonia are on the rise possibly due to the performance measure.

  Developer response: The recent paper by Dr. Lindenauer is useful and informative. CMS has an annual process to maintain and re-evaluate the measures and this process incorporates any important recent literature. The analyses in Dr. Lindenauer's paper suggest some additional cohort codes that could be incorporated into the measure in the future. Because the pneumonia mortality measure has been successfully used in public reporting for four years now and changes to the cohort will have an impact on hospitals and stakeholders, any potential changes must be undertaken with careful consideration. Dr. Lindenauer's paper was a patient-level analysis and our maintenance evaluation will need to take into account the implications for hospital results as well as the potential benefits and risks of changing the cohort definition.

- Request for data on the performance of the risk adjustment model for this measure. It is not clear how readmissions unrelated to the index admission are mitigated in this measure.

  Developer resposne: The NQF application includes substantial data on the performance of the risk-model. As to the question of "unrelated" readmissions, CMS recently developed the algorithm for identifying planned readmissions that is used in the hospital-wide readmission measure. CMS plans to adapt the algorithm for use in the COPD and pneumonia readmission measures. We will bring the updated algorithm and measure results back to the subsequent Steering Committee meeting.

- AHA submitted a letter which is posted on the NQF project page outlining concerns with the following issues:

  - Failure to adjust for factors beyond the hospital's control such as patient characteristics,

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extreme circumstances, patient compliance and quality of post-acute care.

- Reliability – A recent CMS study required by the Accountable Care Act "shows the claims-based measures are unreliable." Additional reliability analyses are provided by KNG showing similar results.
- Harmonization with the recently endorsed measure 1789: Hospital-wide all-cause readmission measure to exclude planned readmissions; harmonization of exclusions in the COPD measures compared to the pneumonia measures that include exclusions for discharged alive on day 0 or 1.
- Exclusions for all Medicare patients in Hospice rather than just FFS Medicare patients enrolled in hospice.

Developer response: Detailed responses to the AHA comments from the developer are posted on the NQF project page. CMS will provide additional information on including exclusions for planned readmissions by July 11 for the Committee to consider.

Steering Commitee Response:

- The Committee reviewed the extensive responses provided by the developer. The Committee indicated that the responses adequately addressed the issues raised by AHA.
- The Committee supports the plan of Yale/CMS to include the algorithm for planned readmissions in measures 0506 and 1891 and looks forward to reviewing the additional data in the next few weeks.
- In response to the comment, CMS/Yale requested additional time to work on harmonization of exclusions using a new algorithm for planned readmission for the all readmission measures, including pneumonia and COPD.

Steering Committee Review – October 16, 2012

- The Committee reviewed the additional information on the algorithm for planned readmissions submitted by Yale CORE.
- The Committee agreed that the list of planned readmission exclusions were reasonable and noted the change in raw readmission rate was less than 1% and the minimal impact on the risk model.
- The Committee unanimously maintained their recommendation for endorsement.

Steering Committee Reassessment of Criteria Met/Suitable for Endorsement: Y-14; N-0

RECOMMEND FOR ENDORSEMENT

Additional Public & Member Comment

- Commenters voiced various concerns including: excluding patients with medical conditions or comorbidities that often require multiple episodes of care; concerns about reliability and potential unintended consequenses.

  Developer response: The measures address clinical differences in hospitals' case-mix through risk adjustment rather than through excluding patients from the measure as suggested by the commenter. The goal in developing outcomes measures is to create a clinically cohesive cohort that includes as many patients as possible admitted with the given condition. Greatly expanding our list of exclusions would result in a measure that was less useful and meaningful, because it would reflect the care of fewer patients and diverse clinical conditions. To fairly profile hospitals' performance, it is critical to place hospitals on a level playing field and account for their differences in the patients that present for care. This is accomplished through adequate risk-adjustment for patients' clinical presentation rather than

exclusion of patients. In addition, the expanded planned readmission definitions for the measures will identify as planned and not count in the outcome readmissions for procedures for procedures, such as wound debridement, that represent routine care for patients with chronic conditions.

We appreciate the points AHA raises about reliability. In a June 19, 2012 memo to NQF we responded to the KNH Health Consulting work in detail. We note that CMS uses 3 years of data to calculate the measure results for the Inpatient Quality Reporting and Hospital Readmission Reduction programs to increase the measures' reliability.

- Additional comments were received voicing concerns incuding: distinguishing between related and unrelated admissions; accounting for socioeconomic factors; and use of hierarchical modeling in the risk adjustment methodology. A commenter suggested that there is an opportunity to use the field experience going forward to determine whether additional changes are warranted and request that the developer provide an assessment at the annual update.

  Developer response: We agree that the field experience with the measures can be informed by the planned readmission algorithm. We made several revisions to the algorithm based on input from the national dry run of CMS's hospital-wide readmission measure. We will continue to evaluate potential additional changes identified by hospitals as the measures are tested and used in CMS programs.
- A commenter commended the NQF, the Steering Committee and the measure developer (Yale/CMS) for their consideration of the concerns voiced by the AHA and other stakeholders during the initial project comment period in June 2012.
- A commenter recommended that the exclusion/inclusion selection criteria methodology be improved with frequent reviews and revisions. Unplanned readmissions that are not related to the index admission should be excluded from this measure and the measure be controlled for socioeconomic status, nonreversible comorbidities, and circumstances outside of the control of the provider.

  Developer Response: The pneumonia readmission measure was developed to be an all-cause measure for several reasons. There are several reasons for using all cause readmission as the outcome. First, from the patient perspective, readmission from any cause is an adverse event. Second, although we would expect few hospitals to use gaming strategies, measures should not create incentives for them to do so. Limiting the measures to readmissions for pneumonia related admissions only may make it susceptible to gaming by coding readmissions with a different diagnosis. Third, it is often hard to exclude quality issues and accountability based on the documented cause of readmission.

  The measure does not adjust for patient characteristics such as socioeconomic status (SES). The association between SES and health outcomes can be due, in part, to the differences in the quality of health care. Risk-adjusting for patient characteristics such as SES would suggest that hospitals with high proportions of such patients are held to different standards for the risk of readmission than hospitals treating higher-SES patient populations. For example, if patients of low socioeconomic status have higher readmission rates, then adjusting for SES in the model will lower the risk-standardized rates for hospitals with a higher proportion of these patients relative to other hospitals with clinically similar patients and similar outcomes. CMS does not want to hold hospitals with different SES mixes to different standards. Adjusting for SES would also obscure differences that are important to identify if we want to reduce disparities where they do exist. Thus, the choice was to adjust only for clinical differences in the populations among hospitals. This is consistent with guidance from the National Quality Forum recommending against adjusting for patient characteristics such as socioeconomic status in outcomes measures.
- General support of the measure.
- A commenter requested a formal evaluation of the qualifying readmissions in the first year of the

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Readmission Reduction Program to determine if there should be further modifications to the planned readmission methodology.

Developer response: We appreciate the AAMC's request for a "formal review" of the planned readmission algorithm in the first year of the Readmission Reduction Program. We note that the algorithm has undergone four rounds of public comment, as well as structured input from surgical subspecialists, technical expert panels, NQF committees, and hospitals participating in a national dry run of the hospital-wide and hip and knee arthroplasty readmission measures. The developer and CMS welcome continued comments and suggestions on the components of the algorithm as the revised measures are used.

Steering Committee Response: The Committee reviewed the comments and responses from developers and made no changes to their recommendations.