

MEASURE WORKSHEET

This document summarizes the evaluation of the measure as it progresses through NQF's Consensus Development Process (CDP). The information submitted by measure developers/stewards is included after the Brief Measure Information, Preliminary Analysis, and Pre-meeting Public and Member Comments sections.

To navigate the links in the worksheet: Ctrl + click link to go to the link; ALT + LEFT ARROW to return

Purple text represents the responses from measure developers.

Red text denotes developer information that has changed since the last measure evaluation review.

Brief Measure Information

NQF #: 1891

Corresponding Measures:

De.2. Measure Title: Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services

De.3. Brief Description of Measure: The measure estimates a hospital-level 30-day, all-cause, risk-standardized readmission rate (RSRR) for patients aged 65 and over discharged from the hospital with either a principal discharge diagnosis of COPD or a principal discharge diagnosis of respiratory failure with a secondary diagnosis of acute exacerbation of COPD. The outcome (readmission) is defined as unplanned readmission for any cause within 30 days of the discharge date for the index admission (the admission included in the measure cohort). A specified set of planned readmissions do not count in the readmission outcome. CMS annually reports the measure for patients who are 65 years or older and are enrolled in fee-for-service (FFS) Medicare and hospitalized in non-federal hospitals or are patients hospitalized in Veterans Health Administration (VA) facilities.

1b.1. Developer Rationale: The goal of this measure is to improve patient outcomes. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Readmissions following COPD are influenced by complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment; several studies have demonstrated that appropriate, timely, and high-quality treatment can contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

By providing patients, physicians, hospitals, and policy makers with information about hospital-level, riskstandardized readmission rates following hospitalization for COPD, COPD readmission is a priority area for outcomes measure development, as it is an outcome that is likely attributable to care processes and is an important outcome for patients. Measuring and reporting readmission rates will inform healthcare providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. The measure will also provide patients with information that could guide their choices, as well as increase transparency for consumers.

S.4. Numerator Statement: The outcome for this measure is 30-day readmission. We define readmission as an inpatient admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index admission for patients discharged from the hospital with a principal discharge diagnosis of COPD or principal discharge diagnosis of respiratory failure with a secondary discharge diagnosis of acute exacerbation of COPD. If a patient has more than one unplanned admission (for any reason) within 30 days after discharge from the index admission, only the first one is counted as a readmission. The measure looks for a dichotomous yes or no outcome of whether each admitted patient has an unplanned readmission within 30 days. However, if the first readmission after discharge is considered planned, any subsequent unplanned readmission is not counted as an outcome for that index admission because the unplanned readmission could be related to care provided during the intervening planned readmission rather than during the index admission.

S.6. Denominator Statement: The cohort includes admissions for patients aged 65 or older, who have been discharged from the hospital with either a principal discharge diagnosis of COPD OR a principal discharge diagnosis of respiratory failure with a secondary discharge diagnosis of acute exacerbation of COPD and with a complete claims history for the 12 months prior to admission.

Additional details are provided in S.9 Denominator Details.

S.8. Denominator Exclusions: The 30-day COPD readmission measures exclude index admissions for patients:

- 1. Without at least 30 days post-discharge enrollment in FFS Medicare (in the case of patients who are not VA beneficiaries);
- 2. Discharged against medical advice (AMA); and,
- 3. Admitted within 30 days of a prior index admission for COPD.

De.1. Measure Type: Outcome

S.17. Data Source: Claims, Enrollment Data, Other

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 06, 2013 Most Recent Endorsement Date: Dec 09, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? This measure is paired with a measure of hospital-level 30-day, all-cause, riskstandardized mortality (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization.

Preliminary Analysis: Maintenance of Endorsement

To maintain NQF endorsement endorsed measures are evaluated periodically to ensure that the measures still meets the NQF endorsement criteria ("maintenance"). The emphasis for maintaining endorsement is focused on how effective the measure is for promoting improvements in quality. Endorsed measures should have some experience from the field to inform the evaluation. The emphasis for maintaining endorsement is noted for each criterion.

1a. <u>Evidence</u>

Maintenance measures – less emphasis on evidence unless there is new information or change in evidence since the prior evaluation.

1a. Evidence. The evidence requirements for a health outcome measure include providing empirical data that demonstrate a relationship between the outcome and at least one healthcare structure, process, intervention, or service; if these data not available, data demonstrating wide variation in performance, assuming the data are from a robust number of providers and results are not subject to systematic bias. For measures derived from patient report, evidence also should demonstrate that the target population values the measured outcome, process, or structure and finds it meaningful.

Summary of prior review in 2016

- During the last review in 2016, the developer attested that there have been no changes in the evidence since the measure was last evaluated in 2013 and the Standing Committee agreed that there was no need for a discussion on evidence and accepted the previous vote.
- Developer provides a logic model depicting that the risk of readmission can be decreased through improving health status and healthcare and support management by delivering timely, high-quality care, reducing the risk of infection and other complications, ensuring the patient is ready for discharge, improving communication among providers involved at care transition, reconciling medications, educating patients about symptoms, whom to contact with questions, and where/when to seek follow-up care and encouraging strategies that promote disease management.
- The developer stated that COPD ranked fourth out of seven conditions associated with the costliest potentially preventable readmissions in Medicare Payment Advisory Committee (MedPAC)'s report to Congress. They referenced a study showing COPD to be a leading cause of hospital readmissions.
- The developer cited studies that demonstrated that guideline recommended care, high-quality and timely treatment for COPD patients can reduce the risk of readmission within 30 days of hospital discharge. They specified one that showed declining readmission rates provides further support for the concept that improvement in transitional care can affect a patient's risk of readmission.
- The developer reported findings that though current hospital interventions can decrease risk
 of readmission, they do not capture all the ways that care within the hospital might influence
 outcomes. They referenced an article that indicated many stakeholders, including patient
 organizations, are interested in outcomes measures that allow patients and providers to assess
 relative outcomes performance for hospitals.
- The developer reported that studies of integrated care management after hospitals discharge have suggested clinical benefit.

Changes to evidence from last review

□ The developer attests that there have been no changes in the evidence since the measure was last evaluated.

It he developer provided updated evidence for this measure:

Updates:

• The developer added that COPD accounts for more than 77,000 readmissions among Medicare patients and costs all payers more than 900 million dollars a year. Furthermore, studies estimated project total costs of COPD treatment to increase to almost \$50 billion dollars by 2020, primarily due to disease complexity, lengthy hospital admissions, and increased prevalence of comorbid conditions.

- The developer cited a public report for July 2015-June 2018, showing 30-day risk-standardized readmission rates ranged from 15.8% to 26.1% for patients admitted with COPD. They stated that readmission rates following COPD discharge are high and variable across hospitals.
- The developer referenced data showing many current hospital interventions like quality improvement projects, are known to decrease the risk of readmission within 30 days of hospital discharge.
- The developer reported that Wake Forest Baptist Medical Center showed promising reductions in readmissions after implementing a comprehensive care plan focused on transitions of care, treatment of comorbidities, and appropriate and timely hospice and palliative care services for COPD patients.

Question for the Committee:

- Does the Standing Committee agree that the evidence demonstrates interventions that providers can implement towards the improvement of patient outcomes and measure performance?
- Does the Committee believe the developer's interventions are meaningful?

Guidance from the Evidence Algorithm

BOX 1: Measure an outcome (Yes) \rightarrow BOX 2: Empirical evidence to support the relationship to a at least one structure or process (Yes) \rightarrow PASS

Preliminary rating for evidence: 🛛 Pass 🗆 No Pass

1b. Gap in Care/Opportunity for Improvement and 1b. Disparities

Maintenance measures - increased emphasis on gap and variation

1b. *Performance Gap.* The performance gap requirements include demonstrating quality problems and opportunity for improvement.

• The developer provided Medicare claims and VA administrative data (n= 825,497 admissions from 4,643 hospitals) data showing variation from July 1, 2016 to June 30, 2019 in hospital-level risk standardized readmission rates (RSRRs). There was a mean of 19.6% and range from 15.5-26.8% in the study cohort. As shown below, the median risk-standardized rate is 19.6%.

Disparities

- The developer provided Medicare FFS claims, VA data, and Medical Beneficiary Summary File (MBSF) data from July 2016 through June 2019 showing variation in RSRRs across hospitals (with at least 25 cases) by proportion of patients with social risk. Hospitals with a lower proportion of dual eligible patients (first quartile) had a median performance of 19.5%, whereas hospitals with a higher proportion of dual eligible patients (forth quartile) had a median performance of 19.6%.
 - Distribution of 30-day COPD RSRRs by Proportion of Dual-Eligible Patients:
- The developer provided Medicare FFS claims, VA data, and The American Community Survey (2013-2017) data from July 2016 through June 2019 showing variation in RSRRs across hospitals (with at least 25 cases) by proportion of patients in lower and upper social risk quartiles. Hospitals with a lower proportion of patients with AHRQSES index scores (first quartile) had a median performance of 19.5%, whereas hospitals with a higher proportion of patients with AHRQ SES index scores (forth quartile) had a median performance of 19.7%.

Questions for the Committee:

• Does the SC agree that there a gap in care that warrants a national performance measure?

Preliminary rating for opportunity for improvement: \Box High \boxtimes Moderate \Box Low \Box Insufficient

Committee Pre-evaluation Comments:

Criteria 1: Importance to Measure and Report (including 1a, 1b, 1c)

1a. Evidence to Support Measure Focus: For all measures (structure, process, outcome, patient-reported structure/process), empirical data are required. How does the evidence relate to the specific structure, process, or outcome being measured? Does it apply directly or is it tangential? How does the structure, process, or outcome relate to desired outcomes? For maintenance measures – are you aware of any new studies/information that changes the evidence base for this measure that has not been cited in the submission? For measures derived from a patient report: Measures derived from a patient report must demonstrate that the target population values the measured outcome, process, or structure.

- Used in public reporting and payment
- pass (sufficient evidence)
- No concerns
- Developer provided continued evidence for the ongoing need for this measure
- I am not aware of any new studies/information that changes the evidence base for this measure
- The evidence provided supports this outcome measure. I am not aware of any new information related to this measure
- Causes of readmission are complex and multifactorial. Many hospitals have processes in place to 'adjust' their readmission rates (e.g. 'skilled nursing units', prolonged hospitalization to avoid readmits, etc.). I have concerns about the evidence to support this measure.

1b. Performance Gap: Was current performance data on the measure provided? How does it demonstrate a gap in care (variability or overall less than optimal performance) to warrant a national performance measure? Disparities: Was data on the measure by population subgroups provided? How does it demonstrate disparities in the care?

- 10th-90th percentile is 18.5-20.8, 2.3 percentage point diff, ~10% diff. Of 3746 hosps with sufficient cases to assess, only 14 better national avg, 52 worse. Limited differentiation
- They provided a study cohort's variation, but would like confirmation that is variation from full data across all hospitals measured in that time period for Medicare and VA and not a sample. Such data should be readily available.
- No concerns
- Data provided to support performance gaps
- Yes. Variability presents an opportunity for improvement. Disparities noted by Proportion of Dual Eligible Patients, across hospitals (with at least 25 cases) by proportion of patients with social risk// Description of Social Risk Variable//Dual Eligibility, by Proportion of Patients with AHRQSES Index Scores
- Performance data showed variations in hospital-level risk standardized readmission rates Dual eligible status and AHRQ SES index were used to measure social risk factors (SFRs).
- The readmission performance gap seems modest ranging between 17 and 24 percent with only a 13% difference between highest and lowest performing hospitals. This performance gap seems modest at best and may not provide optimal discrimination between hospitals.

Criteria 2: Scientific Acceptability of Measure Properties

2a. Reliability: Specifications and Testing

2b. Validity: <u>Testing</u>; <u>Exclusions</u>; <u>Risk-Adjustment</u>; <u>Meaningful Differences</u>; <u>Comparability</u>; <u>Missing Data</u>

Reliability

2a1. Specifications requires the measure, as specified, to produce consistent (reliable) and credible (valid) results about the quality of care when implemented. For maintenance measures – no change in emphasis – specifications should be evaluated the same as with new measures.

2a2. *Reliability testing* demonstrates if the measure data elements are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period and/or that the measure score is precise enough to distinguish differences in performance across providers. For maintenance measures – less emphasis if no new testing data provided.

Validity

2b2. Validity testing should demonstrate the measure data elements are correct and/or the measure score correctly reflects the quality of care provided, adequately identifying differences in quality. For maintenance measures – less emphasis if no new testing data provided.

2b2-2b6. Potential threats to validity should be assessed/addressed.

Composite measures only:

2d. Empirical analysis to support composite construction. Empirical analysis should demonstrate that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct.

Complex measure evaluated by Scientific Methods Panel? oxtimes Yes \Box No

Evaluators: NQF Scientific Methods Panel

SMP Rating:

R: H-1; M-4; L-3; I-0 (Pass) V: H-0; M-6; L-2; I-0 (Pass) Methods Panel Review (Combined)

Methods Panel Evaluation Summary:

This measure was reviewed by the Scientific Methods Panel and discussed on the call. A summary of the measure and the Panel discussion is provided below.

Reliability

• Method(s) of reliability testing:

- The developer conducted measure score reliability testing using claims, Census Data/American Community Survey, VHA Administrative Data, and Master Beneficiary Summary File data from 2008-2019 at the hospital level of analysis.
- The measure developer estimated the overall measure score reliability by calculating the intraclass correlation coefficient (ICC) using a split sample (i.e. test-retest) method before estimating the facility-level reliability (signal-to-noise reliability).

• Reliability testing results:

- Split-sample reliability testing:
- \circ The developer calculated an intra-class correlation coefficient (ICC) of 0.406.
- Signal-to-noise reliability testing:
- \circ The developer reported signal-to-noise reliability scores ranging from 0.11 to 0.90, a median of

0.43 demonstrating moderate agreement. The interquartile range is 0.34 and 0.73.

Validity •

Method(s) of validity testing:

Empirical validity

- The developer identified and assessed the measure's correlation with other measures that target the same domain of quality (e.g., complications, safety, or post-procedure utilization) for the same or similar populations.
- The developer examined the relationship of performance the COPD readmission measure scores (RSRR) had with Hospital Star Rating Readmission group score than the Overall Hospital Star Ratings. For the external measures, the comparison was against performance within quartiles of the Readmission group score, or in the case of Star Ratings, to the Star Rating category (1-5 Stars).
- Face validity as Determined by TEP
 - The developer convened a Technical Expert Panel (TEP), which included 11 members including individuals with diverse perspectives and backgrounds, including clinicians, consumers, hospitals, purchasers, and experts in quality improvement to systematically assess the face validity of the measure score as an indicator of quality by soliciting the TEP members' agreement with the following statement: "The risk-standardized readmission rates obtained from the COPD readmission measure as specified will provide an accurate reflection of quality".

• Validity testing results:

- The correlation between:
 - COPD RSRRs and Star Rating Readmissions score is -0.442, which led the developer to suggest that hospitals with lower COPD RSRRs are more likely to have higher Star Rating Readmission scores.
 - COPD RSRRs and Star Rating summary score is -0.286, which led the developer to suggest that hospitals with lower COPD RSRRs are more likely to have higher Star Rating summary scores.
- The developer states that the results of this validation approach demonstrate an observed trend of lower risk-standardized readmissions with higher star ratings, which supports measure score validity.
- The developer states that the correlation coefficients associated with both the Star Ratings Readmission domain and overall star ratings with the COPD readmission measure indicate moderate associations.
- TEP members convened by the developer reported face validity results that on a six-point scale that the measure will provide an accurate reflection of quality (1=Strongly disagree, 2=Moderately disagree, 3=Somewhat disagree, 4=Somewhat agree, 5=Moderately agree, 6=Strongly agree). Ten of 11 TEP members responded to the survey question as follows: one TEP member Strongly Disagreed, two Somewhat Agreed, four Moderately Agreed, and three Strongly Agreed. Of the TEP members who responded, 90% agreed (70% moderately or strongly agreed) that the measure will provide an accurate reflection of quality.
- Exclusions
 - The developer excluded patients who are discharged AMA, who did not have at least 30 days postdischarge enrollment in FFS Medicare for index admissions, and those with admissions within 30 days of a prior index admission.
 - The developer reported that these exclusions accounted for 0.77%, 0.69%, and 7.05% of all index admissions excluded from the initial index cohort, respectively.
- Risk adjustment Summary:
 - The measure developer utilized a statistical risk model with 40 risk factors, assessing model performance with discrimination and calibration statistics.
 - The developer used a two-stage approach in selecting risk factors for adjustment, first identifying the comorbidity or clinical status risk factors that were most important in predicting the outcome, then considering the potential addition of social risk factors.
 - The social risk variables considered for risk adjustment were the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) index and dual eligibility variables. The developer

states that they aim to capture the social risk factors that are likely to influence income, education, housing, and community factors.

- However, due to the results of a decomposition analysis, the developer stated that CMS chose not to include these two SRFs in the final risk model at this time. The developer noted that adjustment for these factors did not have a material impact on hospital RSRRs, suggesting that existing clinical risk factors capture much of the risk related to social risk.
 - The developer reports that in 2020, dual-eligibility and the AHRQSES index have effect sizes (odds ratios) of 1.07 and 1.06 when added independently to the model.
 - Furthermore, the effect size of each variable is attenuated (1.06 and 1.05 for dual and SES) when both are added to the model.

Questions for the Committee regarding reliability:

- The Committee should discuss the reliability testing results, including the results of the lower tail of the reliability IQR
- Do you have any concerns that the measure can be consistently implemented (i.e., are measure specifications adequate)?
- The Scientific Methods Panel is satisfied with the reliability analyses for the measure. Does the Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Do you have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Committee should discuss the developer's approach to social risk adjustment and the rationale for not including social risk factors in the final model.
- The Scientific Methods Panel is satisfied with the validity analyses for the measure. Does the Committee think there is a need to discuss and/or vote on validity?

Preliminary rating for reliability:	🗆 High	🛛 Moderate	🗆 Low	🛛 Insufficient
Preliminary rating for validity:	🗆 High	🛛 Moderate	🗆 Low	Insufficient

Committee Pre-evaluation Comments: Criteria 2: Scientific Acceptability of Measure Properties (including all 2a, 2b, and 2c)

2a1. Reliability-Specifications: Which data elements, if any, are not clearly defined? Which codes with descriptors, if any, are not provided? Which steps, if any, in the logic or calculation algorithm or other specifications (e.g., risk/case-mix adjustment, survey/sampling instructions) are not clear? What concerns do you have about the likelihood that this measure can be consistently implemented?

- No issues
- no concerns with specs
- No concerns
- No concerns
- No concerns. The measure is well defined and precisely specified.
- I don't have any concerns about the consistent implementation of this measure
- Given the narrow gap between high and low performers, a small error/inaccuracy in classification might impact the performance category. I am not convinced of the reliability of this indicator.
- 2a2. Reliability Testing: Do you have any concerns about the reliability of the measure?
 - Yes. Split sample 0.406 median s/n 0.43. Low in terms of differentiating. Of 3740 hospitals with enough cases to include, only 14 are identified as better than national, 52 worse.

- demonstrated moderate agreement
- No concerns
- No concerns
- No
- No. Two types of reliability testing was done. Moderate reliability
- Yes. See 5.2a1 above.

2b1. Validity -Testing: Do you have any concerns with the testing results?

- No
- It says they used a comparison assessment with the Star Ratings Readmission measure group score and with overall Star Ratings – but those ratings use this measure, so it's not surprising that they saw correlations between scores on the measure those scores that use the measure. Would like more details on that approach.
- No concerns
- No concerns
- No
- No
- Comparisons between star-ratings and RSRR suggests a level of face validity.

2b2-3. Other Threats to Validity (Exclusions, Risk Adjustment) 2b2. Exclusions: Are the exclusions consistent with the evidence? Are any patients or patient groups inappropriately excluded from the measure? 2b3. Risk Adjustment: If outcome (intermediate, health, or PRO-based) or resource use performance measure: Is there a conceptual relationship between potential social risk factor variables and the measure focus? How well do social risk factor variables that were available and analyzed align with the conceptual description provided? Are all of the risk-adjustment variables present at the start of care (if not, do you agree with the rationale provided)? Was the risk adjustment (case-mix adjustment) appropriately developed and tested? Do analyses indicate acceptable results? Is an appropriate risk-adjustment strategy included in the measure?

- C stat 0.639 model has some but not substantial differentiation.
- Concern about not using social risk factors
- No concerns
- Risk adjustment captured by AHRQ SES and dual eligibility
- Yes
- Social risk factors were analyzed but was not included as recommended by ASPE 2020
- Study group seems robust without significant numbers of exclusions. Social risk factors are incorporated into the analysis and the case-mix adjustment seems appropriate. The Authors management of social risk factors is unique but probably OK. A statistician should review the incorporation of social risk factors into the models.

2b4-6. Threats to Validity (Statistically Significant Differences, Multiple Data Sources, Missing Data) 2b4. Meaningful Differences: How do analyses indicate this measure identifies meaningful differences about quality? 2b5. Comparability of performance scores: If multiple sets of specifications: Do analyses indicate they produce comparable results? 2b6. Missing data/no response: Does missing data constitute a threat to the validity of this measure?

- No
- no comment
- No concerns
- Comparability noted

- No
- Hospital Star Rating readmission group score and Overall Hospital Star Rating correlation to COPD RSRRs were used to establish validity.
- Missing data does not seem to be a problem. External validation of performance scores seems ok. I
 have some concerns that this metric identifies meaningful differences given a rather narrow gap
 between high and low performers.

Criterion 3. Feasibility

Maintenance measures - no change in emphasis - implementation issues may be more prominent

- **3.** *Feasibility* is the extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.
 - The developer reports that all data elements are in defined fields in electronic claims and are coded by someone other than person obtaining original information.
 - The developer states that this measure uses administrative claims and enrollment data and as such, offers no data collection burden to hospitals or providers.

Questions for the Committee:

None

Preliminary rating for feasibility: 🛛 High 🛛 Moderate 🖓 Low 🖓 Insufficient

Committee Pre-evaluation Comments: Criteria 3: Feasibility

- 3. Feasibility: Which of the required data elements are not routinely generated and used during care delivery? Which of the required data elements are not available in electronic form (e.g., EHR or other electronic sources)? What are your concerns about how the data collection strategy can be put into operational use?
 - No concerns. Administrative data measure
 - no feasibility concerns
 - No concerns
 - Feasible via claims data
 - None
 - No concerns. The measure uses administrative claims and enrollment data already collected by hospitals
 - Data elements are commonly available. Data collection might be a problem given the model dependence on social risk factors that are not commonly accounted for in typical hospital admissions.

Criterion 4: Usability and Use

Maintenance measures – increased emphasis – much greater focus on measure use and usefulness, including both impact/improvement and unintended consequences

4a. Use (4a1. Accountability and Transparency; 4a2. Feedback on measure)

4a. Use evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4a.1. Accountability and Transparency. Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

Current uses of the measure		
Publicly reported?	🛛 Yes 🛛	Νο
Current use in an accountability program?	🛛 Yes 🛛	No 🗆 UNCLEAR

Accountability program details

The measure is part of the Centers for Medicare and Medicaid Services (CMS) public reporting
program, <u>Hospital Compare</u>, and accountability program <u>Hospital Readmission Reduction Program</u>
(<u>HRRP</u>).

4a.2. Feedback on the measure by those being measured or others. Three criteria demonstrate feedback: 1) those being measured have been given performance results or data, as well as assistance with interpreting the measure results and data; 2) those being measured and other users have been given an opportunity to provide feedback on the measure performance or implementation; 3) this feedback has been considered when changes are incorporated into the measure

Feedback on the measure by those being measured or others

- The measured entities (acute care hospitals) and other stakeholders or interested parties submit questions or comments about the measure through an email inbox.
- The developer also states that they routinely scan literature for scholarly articles describing research related to this measure and summarize new information every 3 years as a part of comprehensive reevaluation as mandated by the Measure Management System (MMS) Blueprint.
- Each year, issues raised through the Q&A or in the literature related to this measure are considered by measure and clinical experts.
 - Any issues that warrant additional analytic work due to potential changes in the measure specifications are addressed as a part of annual measure reevaluation.
 - If small changes are indicated after additional analytic work is complete, those changes are usually incorporated into the measure in the next measurement period.
 - If the changes are substantial, CMS may propose the changes through rulemaking and adopt the changes only after CMS received public comment on the changes and finalizes those changes in the IPPS or other rule.
- Several requests and questions about specifications and interpretation of results were provided through this work. The developer states that there were no questions or issues raised by stakeholders requiring additional analysis or changes to the measure since the last endorsement maintenance cycle.

Questions for the Committee:

• How has the measure been vetted in real-world settings by those being measured or others?

Preliminary rating for Use: 🛛 Pass 🗌 No Pass

4b. Usability (4a1. Improvement; 4a2. Benefits of measure)

4b. Usability evaluate the extent to which audiences (e.g., consumers, purchasers, providers, policymakers) use or could use performance results for both accountability and performance improvement activities.

4b.1 Improvement. Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated.

Improvement results

- The developer stated that the median hospital 30-day, all-cause, RSRR for the COPD readmission measure for the 3-year period between July 1, 2016 and June 30, 2019 was 19.6%. The median RSRR increased by 0.1 absolute percentage points from July 2016-June 2017 (median RSRR: 19.5%) to July 2018-June 2019 (median: RSRR: 19.6%).
- The developer expected an increase in the observed COPD readmission rate between 2017-2018 due to a worse than normal flu season, though flu severity was moderate from 2018-2019 (CDC). Overall, COPD mortality rates appear to be fairly stable after years of decline.

4b2. Benefits vs. harms. Benefits of the performance measure in facilitating progress toward achieving highquality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

Unexpected findings (positive or negative) during implementation

• The developer did not report any unexpected findings.

Potential harms

• The developer did not report any potential harms.

Questions for the Committee:

- How can the performance results be used to further the goal of high-quality, efficient healthcare?
- Does the committee foresee any potential unintended consequences?

Preliminary rating for Usability and use:	🛛 High	🛛 Moderate	🗆 Low	Insufficient
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Committee Pre-evaluation Comments: Criteria 4: Usability and Use

4a1. Use - Accountability and Transparency: How is the measure being publicly reported? Are the performance results disclosed and available outside of the organizations or practices whose performance is measured? For maintenance measures - which accountability applications is the measure being used for? For new measures - if not in use at the time of initial endorsement, is a credible plan for implementation provided? 4a2. Use - Feedback on the measure: Have those being measured been given performance results or data, as well as assistance with interpreting the measure results and data? Have those being measured or other users been given an opportunity to provide feedback on the measure performance or implementation? Has this feedback has been considered when changes are incorporated into the measure?

- Standard feedback: score, rank, detail on cases included in analysis. But ability of measure to differentiate is small. Concerned hospitals are being asked to assess noise.
- no use concerns
- No concerns
- Maintenance measure and has been used in Hospital Compare/Hospital Readmission Reduction Program
- Yes

- Current use on various publicly available websites including Hospital Compare and Hospital Readmission Reduction Program. Feedback was reviewed. No changes made to measure
- I cannot see that feedback about ease of measurement, or measure performance details were given to users. Hence feedback is minimal.

4b1. Usability – Improvement: How can the performance results be used to further the goal of high-quality, efficient healthcare? If not in use for performance improvement at the time of initial endorsement, is a credible rationale provided that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations? 4b2. Usability – Benefits vs. harms: Describe any actual unintended consequences and note how you think the benefits of the measure outweigh them.

- No obvious harms.
- Interested in higher readmission rates observed with a worse than normal flu season does this suggest an issue with the risk adjustment model. also raises questions of how measure will account for COVID-19 pandemic.
- No concerns
- No potential harm noted
- The benefits outweigh any unintended consequences
- No harms identified. Studies indicate potential improvement in the readmission rates for patients hospitalized with other diagnosis. Systematic implementation of quality performance measures across diagnosis may reduce overall readmission rates
- usability might be a problem given the multiple social and environmental elements in the risk model.

Criterion 5: Related and Competing Measures

Related or competing measures

The following measures are all related, though not necessarily competing:

- 0275 : Chronic Obstructive Pulmonary Disease (COPD) or Asthma in Older Adults Admission Rate (PQI 05)
- 0506 : Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization
- 1789 : Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)
- 1893 : Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization
- 2879 : Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and Electronic Health Record Data
- 2888 : Accountable Care Organization Risk-Standardized Acute Hospital Admission Rate for Patients with Multiple Chronic Conditions

Harmonization:

- The developer states that the measure is harmonized to the fullest extent with these measures.
- The developer did not list any non-outcome (e.g., process) measures with the same target population as their measure. Since this is an outcome measure, the developer asserted that clinical coherence of the cohort takes precedence over alignment with related non-outcome measures, which are also limited due to broader patient exclusions.

Committee Pre-evaluation Comments: Criterion 5: Related and Competing Measures

5. Related and Competing: Are there any related and competing measures? If so, are any specifications that are not harmonized? Are there any additional steps needed for the measures to be harmonized?

- No
- all-cause readmissions measures and impacts should be discussed
- No concerns
- Measure harmonized
- Yes and they are harmonized to the extent possible
- There are competing measures. Harmonization done to furthest extent
- There are likely some redundancies between this model and others (e.g. Pneumonia readmit & Chronic Conditions readmit)

Public and Member Comments

Comments and Member Support/Non-Support Submitted as of: 01/21/2021

Comment by: American Medical Association

The American Medical Association (AMA) appreciates the opportunity to comment on NQF Quality Positioning System (QPS) Measure #1891, Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization. This is an important measure which captures the unplanned readmission for any reason within 30 days of a patient's discharge from the hospital.

The AMA is disappointed to see the minimum measure score reliability results calculated at 0.11 and the intraclass correlation coefficient (ICC) calculated at 0.406 using a minimum case number of 25 patients. We believe that measures must meet <u>minimum</u> acceptable thresholds of 0.7 for reliability and require higher case minimums to allow the overwhelming majority of hospitals to achieve an ICC of 0.6 or higher.

The AMA is also extremely concerned to see that the measure developer used the recommendation to exclude social risk factors in the risk adjustment models for measures that are publicly reported as outlined in the recent report to Congress by Assistant Secretary for Planning and Evaluation (ASPE) on Social Risk Factors and Performance in Medicare's Value-based Purchasing program (ASPE, 2020). We believe that while the current testing may not have produced results that would indicate incorporation of the two social risk factors included in testing, this measure is currently used both for public reporting and value-based purchasing. A primary limitation of the ASPE report was that none of the recommendations adequately addressed whether it was appropriate to adjust for social risk factors in the same measure used for more than one accountability purpose, which is the case here. This discrepancy along with the fact that the additional analysis using the American Community Survey is not yet released must be addressed prior to any reliance on the recommendations within this report. We also note that the developer chose to include social risk factors in two measures (#2888 and #3597) under review and we ask that this inconsistency be considered and rectified.

In addition, we question whether the measure continues to be useful to distinguish hospital performance and drive improvements based on the distribution of hospital's performance scores where only 14 hospitals performed better than the national rate and 52 hospital were worse (as noted in section 2b4 and the discussion on improvement in section 4b1 of the measure submission form), and where there was only an increase of 0.1 absolute percentage points between July 2016-June 2017 and July 2018-June 2019.

The AMA requests that the Standing Committee evaluate whether the measure continues to meet the measure evaluation criteria required for endorsement.

Reference:

Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. <u>https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-</u> purchasing-programs

• Comment by: Federation of American Hospitals

The Federation of American Hospitals (FAH) appreciates the opportunity to comment on Measure #1891, Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization. The FAH is concerned that even though the median reliability score was 0.43 for hospitals with at least 25 cases, reliability ranged from 0.11 to 0.90 and that the intraclass correlation coefficients (ICC) was 0.406. The FAH believes that the developer must increase the minimum sample size to a higher number to produce a minimum reliability threshold of sufficient magnitude (e.g. 0.7 or higher) and an ICC of 0.6 or higher.

In addition, the FAH is very concerned to see that the measure developer's rationale to not include social risk factors in the risk adjustment model was in part based on the recommendations from the report to Congress by Assistant Secretary for Planning and Evaluation (ASPE) on Social Risk Factors and Performance in Medicare's Value-based Purchasing program released in March of last year (ASPE, 2020). A fundament flaw within the ASPE report was the lack of any recommendation addressing how a single measure with multiple accountability uses should address inclusion of social risk factors as is the case with this measure, which is both publicly reported and included in the Hospital Value-Based Purchasing program. Regardless of whether the testing of social risk factors produced results that were sufficiently significant, the FAH believes that no developer should rely on the recommendations of this report until the question of how to handle multiple uses is addressed along with the additional analysis using the American Community Survey. We also note that the developer chose to include social risk factors in two measures (#2888 and #3597) under review and we ask that this inconsistency be considered.

Lastly, the FAH is concerned that there is insufficient variation in performance across hospitals and limited opportunities for improvement to support this measure's continued use in accountability programs. Specifically, the performance scores reported in 2b4. Identification of Statistically Significant and Meaningful Difference in Performance are generally low with only 14 hospitals identified as better than the national rate and 52 are worse than the national rate. We base our concerns on these results along with the discussion on improvement in section 4b1 of the measure submission form where only an increase of 0.1 absolute percentage points between July 2016-June 2017 and July 2018-June 2019 was found.

As a result, the FAH requests that the Standing Committee carefully consider whether the measure as specified should continue to be endorsed.

Reference:

Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. <u>https://aspe.hhs.gov/social-risk-factors-and-medicares-value-based-purchasing-programs</u>

- Comment by: Anonymous
 - \circ I support this measure.
 - No NQF Members have submitted support/non-support choices as of this date.

Combined Methods Panel Scientific Acceptability Evaluation

Scientific Acceptability: Preliminary Analysis Form **Measure Number:** 1891

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

Type of measure:

□ Process □ Process: Appropriate Use □ Structure □ Efficiency □ Cost/Resource Use ○ Outcome □ Outcome: PRO-PM □ Outcome: Intermediate Clinical Outcome □ Composite Data Source:

🛛 Claims 🛛 Electronic Health Data 🖓 Electronic Health Records 🖓 Management Data

□ Assessment Data □ Paper Medical Records □ Instrument-Based Data □ Registry Data

Enrollment Data Other -- Panel Member #2 Census Data/American Community Survey, VHA Administrative Data, Master Beneficiary Summary File; Panel Member #6 Medicare enrollment data; Panel Member #9 California All-Payer Dataset

Level of Analysis:

□ Clinician: Group/Practice □ Clinician: Individual ⊠ Facility □ Health Plan

□ Population: Community, County or City □ Population: Regional and State

□ Integrated Delivery System □ Other

Measure is:

□ New ⊠ Previously endorsed (NOTE: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.)

RELIABILITY: SPECIFICATIONS

1. Are submitted specifications precise, unambiguous, and complete so that they can be consistently implemented? \boxtimes Yes \Box No

Submission document: "MIF_xxxx" document, items S.1-S.22

NOTE: NQF staff will conduct a separate, more technical, check of eCQM specifications, value sets, logic, and feasibility, so no need to consider these in your evaluation.

Panel Member #8 measure specs are clear and in line with other CMS measures.

2. Briefly summarize any concerns about the measure specifications.

Panel Member #1 NONE

Panel Member #2 None Panel Member #9 No concerns

RELIABILITY: TESTING

Submission document: "MIF_xxxx" document for specifications, testing attachment questions 1.1-1.4 and section 2a2

3. Reliability testing level 🛛 Measure score 🖾 Data element 🗔 Neither

4. Reliability testing was conducted with the data source and level of analysis indicated for this measure 🛛 Yes 🔲 No

5. If score-level and/or data element reliability testing was NOT conducted or if the methods used were NOT appropriate, was **empirical VALIDITY testing** of **patient-level data** conducted?

□ Yes □ No – Panel Member #1 NA; Panel Member #5 Not Appliable

6. Assess the method(s) used for reliability testing

Submission document: Testing attachment, section 2a2.2

Panel Member #1 S/N model; split sample ICC

Also discussed, number in sample performing better than/worse than national rate

Panel Member #2 Split-sample reliability and signal-to noise analysis.

Panel Member #3 Test-retest & signal to noise – both appropriate for a facility level measure.

Panel Member #4 Developer estimated the overall measure score reliability by calculating the intra-class correlation coefficient (ICC) using a split sample (i.e. test-retest) method and estimated the facility-level reliability using signal-to-noise (Adams)

Panel Member #5 There was clearly a good faith effort to establish reliability of the data elements and measure score.

Panel Member #6 Developers performed two types of reliability testing. First, they estimated the overall measure score reliability by calculating the intra-class correlation coefficient (ICC) using a split sample (i.e.

test-retest using randomly selected subsets of non-overlapping patients for 3-year period) method. Second, they estimated the facility-level reliability (signal-to-noise reliability) to estimate reliability at hospital level. Signal to noise reliability scores can range from 0 to 1 where a reliability of zero indicating that all variability in a measure is attributable to measurement error and a reliability of one implies that all the variability is attributable to real difference in performance. These methods are both accepted approaches.

Panel Member #8 Intraclass-coefficient testing using a split-sample (test-retest)methodology. Spearman-Brown was 0.406.

Signal-noise was calculated for hospitals with at least 25 admissions. The mean reliability score was 0.43, ranging from 0.11 to 0.90. 25th and 75th percentiles were 0.25 and 0.60. The Adams approach gave a reliability score of 0.55.

Panel Member #9 Thorough testing methods using ICC of a split sample to test measure score and additional signal-to-noise for facility level reliability

7. Assess the results of reliability testing

Submission document: Testing attachment, section 2a2.3

Panel Member #1 Split sample test retest statistic 0.406

Missing from the split sample analysis was an analysis that has proven useful in the past to assessing how reliably the measure identifies relative performance, specifically, the quintile to quintile cross tab of hospitals comparing the first sample to the second.

S/N: Median 0.43

S/N: 10th percentile 0.16

S/N: 90th percentile 0.70

Out of 4,643 hospitals in the measure cohort, 14 performed "better than the U.S. national rate," 3,680 performed "no different from the U.S. national rate," and 52 performed "worse than the U.S. national rate." 897 were classified as "number of cases too small" (fewer than 25) to reliably tell how well the hospital is performing.

The 10th-90th percentile RSRRs are 18.5-20.8, a 2.3 percentage point difference. Given the number of cases, this is clinically meaningful but the small range imposes a substantial burden to reliably measure relative performance.

The results of the testing suggests the measure cannot reliably differentiate performance. The split sample test statistic is low against the standard that would differentiate hospitals, the S/N median is low against a standard that would differentiate hospitals. (The Adams S/N analysis made a S/N of 0.7 its defacto standard.) This is also reflected in the small number of hospitals identified as performing better than or worse than the national rate.

Panel Member #2 Split-sample analysis: The agreement between the two independent assessments of the RSRR for each hospital as measured through the Spearman-Brown prediction formula was 0.406. Signal-to-Noise: The median reliability score was 0.43, which demonstrates moderate reliability between the two samples.

Panel Member #3 Taken together, these represent modest to low reliability.

ICC: Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSRR for each hospital was 0.406.

Signal-to-noise: The median reliability score was 0.43, ranging from 0.11 to 0.90.

Panel Member #4 Using a minimum case volume of 25 had moderate reliability

Panel Member #6 Split-Sample Reliability: A total of 825,497 admissions were included in the analysis based on 3 years of data. After randomly splitting the sample into two halves, there were 411,617 admissions from 4,591 hospitals in one half and 413,880 admissions from 4,643 hospitals in the other half. The ICC was calculated for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSRR for each hospital was 0.406.

Signal-to-Noise: The signal-to-noise reliability score was calculated for hospitals with at least 25 admissions. The median reliability score was 0.43, ranging from 0.11 to 0.90. The 25th and 75th percentiles were 0.25 and 0.60, respectively.

The developers indicate the median reliability score demonstrates moderate agreement. However, the ICC of 0.406 is at the LOWER END based on the Landis (1977) scale used. The SMP has expressed concerns about application of this scale especially for values below .50. I would consider this low reliability as agreement is less than 50% of the time.

Panel Member #8 Meets the criteria for moderate reliability.

Panel Member #9 Measure score reliability fell into the mid-range of moderate agreement based on the Landis Koch standards. Signal to noise reliability also demonstrated moderate reliability. Taken in context of their rationale for being acceptable results, I have no issues with the reliability testing and results.

8. Was the method described and appropriate for assessing the proportion of variability due to

real differences among measured entities? NOTE: If multiple methods used, at least one must be appropriate. Submission document: Testing attachment, section 2a2.2

imes Yes

🗆 No

□ Not applicable (score-level testing was not performed)

9. Was the method described and appropriate for assessing the reliability of ALL critical data elements?

Submission document: Testing attachment, section 2a2.2

🛛 Yes

🗆 No

Not applicable (data element testing was not performed)

10. **OVERALL RATING OF RELIABILITY** (taking into account precision of specifications

and all testing results):

High (NOTE: Can be HIGH only if score-level testing has been conducted)

Moderate (NOTE: Moderate is the highest eligible rating if score-level testing has <u>not</u> been conducted)

⊠ **Low** (NOTE: Should rate **LOW** if you believe specifications are NOT precise, unambiguous, and complete or if testing methods/results are not adequate)

□ **Insufficient** (NOTE: Should rate **INSUFFICIENT** if you believe you do not have the information you need to make a rating decision)

11. Briefly explain rationale for the rating of OVERALL RATING OF RELIABILITY and any concerns you may have with the approach to demonstrating reliability.

Panel Member #1 The results of the testing suggests the measure cannot reliably differentiate performance. The split sample test statistic is low against the standard that would differentiate hospitals, the S/N median is low against a standard that would differentiate hospitals. (The Adams S/N analysis made a S/N of 0.7 its defacto standard.) This is also reflected in the small number of hospitals identified as performing better than or worse than the national rate.

Panel Member #2 As indicated in #7 above, both the split-sample analysis and signal-to-noise analysis indicate moderate reliability of the COPD RSRR.

Panel Member #3 I would rate this measure between low and moderate - users of the tool need to be aware that reliability may be an issue, particularly for lower volume facilities.

Panel Member #4 This submission demonstrates integrity in the determination of case volumes for moderate reliability.

Panel Member #5 Reliability testing was adequate. Very low inter-decile distribution of Provider performance may be a problem as was the very low split-half coefficient of 0.43.

Panel Member #6 The scores of both the split sample and signal-to-noise reliability were both well below .70 (mid-point of substantial agreement) at 0.406 and 0.43, indicate low to moderately reliable results at best. The developers indicate this represents "moderate agreement". While I think these scores are too low for measures used in public reporting and value-based payment, there is not yet a threshold cut-off set by the SMP or NQF guidance to allow us to reject a measure with scores below some more generally acceptable threshold such as .7 or .8. I believe we should be setting higher standards for these measures given their importance in determining which hospitals receive penalties or reduced payments based on these measure scores. The developers note that reliability of measures used to define complex constructs

such as clinical severity or patient comorbidities is significantly lower than for simpler constructs such as patient weight.

Panel Member #7 RSRR .424

Taken together, these results indicate that there is moderate reliability in the measure score.

Panel Member #8 Indicated by the split-sample and the signal to noise results.

Panel Member #9 Would rate high if reliability results were higher but as noted above, it is acceptable considering the QM Sterward's rationale.

VALIDITY: ASSESSMENT OF THREATS TO VALIDITY

12. Please describe any concerns you have with measure exclusions.

Submission document: Testing attachment, section 2b2.

Panel Member #1 NONE

Panel Member #2 Reasonable and well-explained exclusions except that I don't get why the restriction that each hospital should have a minimum of 25 of the qualifying admissions is not an exclusion restriction.

Panel Member #4 None

Panel Member #8 Standard Medicare claims data exclusions dominated (7.05%) by the COPD admissions within 30 days of a prior COPD index admission.

Panel Member #9 No concerns

13. Please describe any concerns you have regarding the ability to identify meaningful differences in performance.

Submission document: Testing attachment, section 2b4.

Panel Member #1 The 10th-90th percentile RSRRs are 15.3-17.1, a 1.8 percentage point difference. Given the number of cases, this is clinically meaningful but the small range imposes a substantial burden to reliably measure relative performance.

Panel Member #2 Only 14 or 0.37% (better) and 52 or 1.37% (worse) out of 3746 hospitals with at least 25 COPD admissions were the so-called outliers from the national standard. Thus, I wonder about measure's ability to identify meaningful difference in performance.

Panel Member #4 None

Panel Member #6 The developers report a median odds ratio of 1.13 which they say suggests a meaningful increase in the risk of readmission if a patient is admitted with COPD at a higher risk hospital compared to a lower risk hospital. A ratio indicates that a patient has a 13% increase in the odds of a readmission at higher risk performance hospital compared to a lower risk hospital, indicating the impact of quality on the outcome rate.

They add that the variation in rates and number of performance outliers suggests there remain differences in the quality of care received across hospitals. However, the distribution of rates is not shown, such as differences in rates across deciles or quartiles. I would like to see these data to better understand whether the measure can truly identify "meaningful differences" in performance between hospitals.

Panel Member #8 The intercept methodology that contributes to the hospital specific ratio being from one intercept and the expected value using an all-hospital intercept is new but does lead to 14 being classified as "better than" the national rate, 3,680 being "no different" from the national rate, 52 being "worse than" the national rate, and 897 being too small to classify. The mean odds ratio was 1.13, which implies that being admitted to a higher risk hospital carries a 13% higher risk of readmission than a lower risk hospital.

Panel Member #9 No concerns

14. Please describe any concerns you have regarding comparability of results if multiple data sources or methods are specified.

Submission document: Testing attachment, section 2b5.

Panel Member #1 N/A

Panel Member #3 NA

Panel Member #4 None

Panel Member #6 They are using both Medicare and VA data. I suspect VA data is quite different but I did not see any comparisons or testing to see if the coefficients or model might be different in that

population. The original model in fact was based on CA all payer data, which I am also not convinced is fully representative of the entire nation, CA is quite different. So I still have concerns about how the model was developed originally and what further testing has been done as the model is recalibrated on annual basis.

Panel Member #8 Not applicable.

15. Please describe any concerns you have regarding missing data.

Submission document: Testing attachment, section 2b6.

Panel Member #1 N/A

Panel Member #3 Not reported by measure developers

Panel Member #4 None

Panel Member #8 There was no missing data.

Panel Member #9 N/A

16. Risk Adjustment

16a. Risk-adjustment methodImage: NoneImage: Statistical model - Panel Member #6 40 riskfactorsImage: Stratification

16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses? ⊠ Yes □ No ⊠ Not applicable

16c. Social risk adjustment:

16c.1 Are social risk factors included in risk model? \square Yes \square No \square Not applicable

Panel Member #5 ZIP code level—Area Deprivation Index (ADI) from Census data (2009-2013)

- 16c.2 Conceptual rationale for social risk factors included? \square Yes \square No
- 16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure

focus? 🛛 Yes 🗌 No

16d. Risk adjustment summary:

- 16d.1 All of the risk-adjustment variables present at the start of care? oxtimes Yes $\hfill D$ No
- 16d.2 If factors not present at the start of care, do you agree with the rationale provided for inclusion? ⊠ Yes □ No Panel Member #1 N/A
- 16d.3 Is the risk adjustment approach appropriately developed and assessed? ⊠ Yes □ No **Panel Member #1** Yes, but would like the proportion of variance explained by the risk model in addition to the C-statistic and calibration analysis
- 16d.4 Do analyses indicate acceptable results (e.g., acceptable discrimination and calibration)
- 16d.5. Appropriate risk-adjustment strategy included in the measure? ⊠ Yes □ No **Panel Member #5** See previous comments

16e. Assess the risk-adjustment approach

Panel Member #1 Risk adjustment approach is standard CMSHCC model. C-stat of 0.639 is not high, reflecting limited ability to predict readmission, but in range previously accepted.

SRF's while differentiated across patients and to some extent across hospitals, only explain a small portion of variance and correlation of scores based on risk adjustment model with and without SRFs is 0.998.

Panel Member #2 The C-statistics for the final base model was 0.64, which may not be considered very good fit.

Panel Member #3 The logistic regression model fit is not stellar (0.639), but the addition of the risk deciles and the test for overfitting help build a case for model adequacy.

Panel Member #4 Social risk factors are well conceptualized

Panel Member #5 Risk adjustment was generally adequate, though not exceptional. Presentation of "Social Risk Proportion" (section 1b.4) was confusing. The analyses and discussion of the analyses for social risk factors was extensive. I would caution the Developers that the c-statistic is an overall measure rather than a specific indicator of how social risk adjustment affects the most extreme Providers (i.e., those with very few or very many patients with particular socio-demographic risk factors). An analysis of how the inclusion of socio-demographic risk factors affects the risk adjusted performance of these extreme Providers would be more meaningful than simple differences in c-statistics for the overall population.

Panel Member #6 Developers use a two-stage approach, first identifying the comorbidity or clinical status risk factors that were most important in predicting the outcome, then considering the potential addition of social risk factors. It is not clear why social risk factors were included only in 2nd phase indicating lesser importance to predicting readmissions. They do indicate this is CMS approach, to first consider adjustment for clinical comorbidities and then examine additional risk imparted by SRFs after the potential for greater disease burden is included. They "believe this is consistent with NQF current guidance and is appropriate given the evidence that people with greater social risk are more likely to have more disease burden." They further state that "if clinical risk factors explain all or most of the patient variation in the outcome, then NQF guidance does not support adding social risk factors that do not account for variation." I would recommend the SMP discuss whether they believe this approach is in fact consistent with current NQF guidance.

They first selected all chronic conditions (CCs) deemed relevant to the Medicare population and to the readmission outcome. Final variable selection was accomplished using a modified stepwise logistic regression based on 1,000 bootstrap samples. A logistic stepwise regression including all candidate variables was run on each sample, and they evaluated the percentage of times a candidate variable was significant at p<0.01 level in the models. They included not only variables that exceeded a "predetermined cutoff" (not stated?), but specific variables with particular clinical relevance were "forced" into the model regardless of percent of times significant in the models to ensure appropriate risk adjustment for COPD (e.g., end of life, frailty variables such as pressure ulcers, cancers, stroke, CKD). This resulted in a final risk adjustment model with 40 variables.

As a second stage, the developers assessed the relationship between two social risk factors (SFRs) and the outcome and examined the incremental effect in the multivariable model. They used dual-eligible status and the AHRQSES index as the two SFRs. They assessed the relationship between the SRF variables with the outcome and the incremental effect in a multivariable model (i.e., the extent to which the addition of any one of these variables improved model performance or changed hospital results). As an additional step, they assessed whether there was a "contextual effect" at the hospital level to assure the impact of the SFR on the outcome was not primarily due to differences in hospitals. They used decomposition analysis to assess the independent effects of the SRF variables at the patient level and the hospital level. The clinical variables as noted were not all statistically significant, and many ORs were close to 1.00.

The clinical variables as noted were not all statistically significant, and many ons were close to 1.00. The SFR variables however showed disparities in readmission rates; 2020 observed rate for dual eligible patients was 22.7% (compared to 18.8% for non-duals), and for patients with low AHRQ SES scores 20.9% (compared to 19.2% for high SES patients). They also evaluated the incremental effect of SRF variables on the risk adjustment model, and found effect size (Odds Ratios) of 1.07 and 1.06 when added independently into the model. *NOTE that these ORs are similar to effect of MANY of the clinical factors included in the model*. They found the C-statistic was relatively unchanged with addition of any of the SRF variables (constant at 0.64, which is not necessarily good fit to start with). I would argue that the independent addition of many of the clinical variables included in the model that had ORs closer to 1.00 would also not change the C-statistic.

Finally, they found the addition of SRF variables had little effect on hospital rates. The median absolute change in hospitals' RSRRs when adding a dual eligibility indicator was 0.014% (interquartile range [IQR] - 0.012% - 0.016%) with a correlation coefficient between RSRRs for each hospital with and without dual eligibility added of 0.998. The median absolute change in hospitals' RSRRs when adding a low AHRQ SES Index score indicator to the model was 0.101% (IQR -0.097% - 0.104%) with a correlation coefficient between RSRRs for each hospital with and without an indicator for a low AHRQ SES Index score adjusted for cost of living at the census block group level is 0.975.

The contextual effect analysis of patient level vs. hospital level affects of the SRFs showed both the patientlevel and hospital-level dual eligibility, as well as low AHRQ SES Index effects, were significantly associated with COPD readmissions in the decomposition analysis. They claim that *"the significance of the hospitallevel effects indicates that if dual eligibility or low AHRQ SES Index variables were used to adjust for patientlevel differences, then some of the differences between hospitals would also be adjusted for, potentially obscuring a signal of hospital quality."* I would argue that this is not necessarily true; if appropriate risk adjustment methods are used, the adjustment can be made without losing the hospital effect which differentiates high performing vs. low performing hospitals. Also it appears the AHRQ SES index status effect was much larger at patient level than hospital level based on 2020 parameter estimates, and the patient effect was much larger than the hospital effect for dual status, contrary to their argument. Based on results and recent recommendation in ASPE 2020 report to Congress recommending quality measures are NOT adjusted for SFRs, CMS chose not to include the 2 SRFs in the final model. Based on evidence presented, I am not convinced this decision was correct or consistent with their logic for inclusion of clinical risk factors.

Panel Member #8 Starting with Condition Categories, an expert team reviewed and excluded non-relevant variables. The remainder were used to run a logistic stepwise regression model to derive those significantly associated with readmission. Clinical experts then chose a cutoff level resulting in a final risk-adjustment model of 40 variables. Social risk factors were included, but analysis did not demonstrate a significant contribution to the model. C-statistic was only improved from 0.639 to 0.640 with their inclusion. **Panel Member #9** Very thorough analysis using Dual-Eligibility as a proxy measure for SES and AHRQ's SES Indicators.

For cost/resource use measures ONLY:

17. Are the specifications in alignment with the stated measure intent?

- □ Yes □ Somewhat □ No (If "Somewhat" or "No", please explain)
 - 18. Describe any concerns of threats to validity related to attribution, the costing
 - approach, carve outs, or truncation (approach to outliers):

VALIDITY: TESTING

- 19. Validity testing level: 🛛 Measure score 🖾 Data element 🗖 Both
- 20. Method of establishing validity of the measure score:
- ☑ Face validity
- Empirical validity testing of the measure score
- □ N/A (score-level testing not conducted)
 - 21. Assess the method(s) for establishing validity
- Submission document: Testing attachment, section 2b2.2

Panel Member #1 Correlation STAR ratings

Correlation with STAR ratings overall score

Correlation with AMI EDAC scores

Panel Member #2 Empirical validity was assessed through following correlation measures: Correlation between COPD RSRRs and Star-Ratings Readmission Group Scores (hypothesized relationship: negative) and COPD RSRRs and Overall Star-Ratings Scores (hypothesized relationship: negative).

Panel Member #3 The measure developers focus on validity using two measures from hospitals compare. I appreciate the focused selection of measures and predicted relationship. Would have liked a measure more closely related to COPD.

Panel Member #4 Developer examined correlations with the Start rating readmission scores and summary score

Panel Member #6 Developers identified the measure's correlation with other measures that target the same domain of quality, including the Hospital Star Rating readmission group score measure and the Overall Hospital Star Rating.

They also conducted face validity testing using a technical expert panel.

Panel Member #8 Measure score validity testing consisted exclusively of correlation with two other score measures, namely a correlation between the COPD RSRR and the Star-Ratings Readmission Group Scores, and a correlation between the COPD RSRR's and the Overall Star Ratings Scores. The former had a -0.442 correlation and the latter had a -0.286 correlation.

Panel Member #9 Interesting method of using the Star Ratings given the controversial methodology of calculating the overall Star Ratings.

22. Assess the results(s) for establishing validity

Submission document: Testing attachment, section 2b2.3

Panel Member #1 Correlation with STAR ratings readmission score -.442

Correlation with STAR ratings overall score: -.286

Levels of correlation are sufficient, although the confidence intervals for RSRR across quartiles of STAR ratings substantially overlap.

Panel Member #2 The correlation between COPD RSRRs and Star-Ratings Readmission Group Scores was - 0.442 and COPD RSRRs and Overall Star-Ratings -0.286, which supported the hypothesized relationships with the COPD RSRR.

I am just curious why excess days in acute care for COPD was not considered like the way the developer has done for HF or AMI measures.

Panel Member #3 I liked the fact the readmission measure has a stronger correlation with the readmission measure group than the overall star ratting.

Panel Member #4 The degree of consensus was moderate to low.

Panel Member #5 The measure has been widely used by many researchers in published articles. **Panel Member #6** Correlation between COPD RSRRs and Star-Rating readmissions score was -0.442, indicating hospitals with lower readmission rates were somewhat more likely to have higher Star-Rating readmission scores as expected. The correlation between RSRRs and the Overall Star-Rating summary score was -0.286, which suggests that hospitals with lower RSRRs are *only slightly more likely* to have higher Star-Rating summary scores as expected.

Face validity results showed moderate agreement that the TEP believed the measure will provide an accurate measure of quality, with 7 of 10 either moderately (4) or strongly (3) agreeing, but 3 strongly or somewhat agreed.

These results support low to moderate measure score validity.

Panel Member #8 Correlation with other scores can be used to establish validity but more formal validity testing would have been more convincing.

Panel Member #9 Moderate correlation of COPD Readmissions with Star Rating scores was demonstrated.

23. Was the method described and appropriate for assessing conceptually and theoretically sound hypothesized relationships?

Submission document: Testing attachment, section 2b1.

⊠ Yes – Panel Member #1 Yes, but see note in 22.

🗌 No

□ Not applicable (score-level testing was not performed)

24. Was the method described and appropriate for assessing the accuracy of ALL critical data

elements? NOTE that data element validation from the literature is acceptable. **Submission document:** Testing attachment, section 2b1.

⊠ Yes – Panel Member #1 We have previously accepted the argument that CMS auditing of data for payment was an acceptable measure of data element accuracy.

🗌 No

Not applicable (data element testing was not performed)

25. **OVERALL RATING OF VALIDITY taking into account the results and scope of all testing and analysis of potential threats.**

□ **High** (NOTE: Can be HIGH only if score-level testing has been conducted)

Moderate (NOTE: Moderate is the highest eligible rating if score-level testing has NOT been conducted)

Low (NOTE: Should rate LOW if you believe that there **are** threats to validity and/or relevant threats to validity were **not** assessed **OR** if testing methods/results are not adequate)

□ Insufficient (NOTE: For instrument-based measures and some composite measures, testing at both the score level and the data element level is required; if not conducted, should rate as INSUFFICIENT.)

26. Briefly explain rationale for rating of OVERALL RATING OF VALIDITY and any concerns you

may have with the developers' approach to demonstrating validity.

27. **Panel Member #1** Measure has face validity and reasonable correlation with other similar measures.

Panel Member #2 See my notes in 16e, 21 and 22.

Panel Member #3 The criterion related validity helps makes the case for the measure, but authors only test one aspect of validity.

Panel Member #4 A demonstration of an implicit quality construct is the lowest level of empirical validity testing or validity maturity level 0. To demonstrate a moderate level, the developer must show an empirical association between the explicit quality construct and the material outcome.

Panel Member #5 Developer demonstrated an effort to risk adjust measure to create valid measure score. Very low inter-decile distribution across Providers (2.3% between 10^{th} and 90^{th} percentiles) may be a problem in discriminating among Providers. I have a personal bias against using the RSRR approach (described in S.14) comparing the "predicted" to the "expected" Provider rates because both values are dependent upon the quality (power and specificity) of the regression models. However, the RSRR methodology has been deemed acceptable by SMP by consensus and I will abide by that decision. Note¹: The applicability of the risk model for only those patients >= 65 vs. >= 40 was tested, although results were marginal. For example, was the distribution of percentile values based on the >= 40 or >=65 group? Only one distribution of percentile values presented. Additionally, item 1.5 in Measure Testing document lists only >= 65 beneficiaries. Same problem with "Signal to Noise" results Table 2.

Note²: Face validity results have no meaning on a measure resubmission and should be deleted from the submission. The relationship between the COPD RSRR values and Star Ratings (by quartile) show virtually no discriminatory value with each RSRR inter-quartile range and median value for each quartile grouping being virtually identical, e.g., median Q1 = approx. 20.0 and median Q4 = approx. 19.5.

Panel Member #6 The validity test results show moderate validity of the model.

Panel Member #7 "We examined the relationship of performance the AMI readmission measure scores (RSRRs) with each of these external measures of hospital quality."

"The correlation coefficients associated with the AMI EDAC, Star Ratings Readmission domain, and Overall Star Ratings summary scores indicate moderate associations, which is to be expected given that all measures are calculated by complex statistical models. Overall, the results above show that the trend and direction of this association is in line with what would be expected."

Panel Member #8 Correlation with STAR scores was utilized. While the associations were negatively correlated to a moderate degree. This Is not unexpected.

Panel Member #9 The QM Stewards demonstrated moderate validity using a unique correlation between the COPD RSRR and the Star Ratings. Given the controversy regarding the accuracy of the Star Ratings and the fact that Yale Core developed the Star Rating methodology, I would have preferred a different method of demonstrating validity.

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

28. What is the level of certainty or confidence that the empirical analysis demonstrates that the component measures add value to the composite and that the aggregation and weighting rules are consistent with the quality construct?

🗌 High

Moderate

🗆 Low

□ Insufficient

29. Briefly explain rationale for rating of EMPIRICAL ANALYSES TO SUPPORT COMPOSITE CONSTRUCTION

ADDITIONAL RECOMMENDATIONS

30. If you have listed any concerns in this form, do you believe these concerns warrant further discussion by the multi-stakeholder Standing Committee? If so, please list those concerns below. Panel Member #6 See comments related to evaluating the risk adjustment findings related to social risk factors.

NQF #: 1891

Corresponding Measures:

De.2. Measure Title: Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following chronic obstructive pulmonary disease (COPD) hospitalization

Co.1.1. Measure Steward: Centers for Medicare & Medicaid Services

De.3. Brief Description of Measure: The measure estimates a hospital-level 30-day, all-cause, risk-standardized readmission rate (RSRR) for patients aged 65 and over discharged from the hospital with either a principal discharge diagnosis of COPD or a principal discharge diagnosis of respiratory failure with a secondary diagnosis of acute exacerbation of COPD. The outcome (readmission) is defined as unplanned readmission for any cause within 30 days of the discharge date for the index admission (the admission included in the measure cohort). A specified set of planned readmissions do not count in the readmission outcome. CMS annually reports the measure for patients who are 65 years or older and are enrolled in fee-for-service (FFS) Medicare and hospitalized in non-federal hospitals or are patients hospitalized in Veterans Health Administration (VA) facilities.

1b.1. Developer Rationale: The goal of this measure is to improve patient outcomes. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Readmissions following COPD are influenced by complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment; several studies have demonstrated that appropriate, timely, and high-quality treatment can contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

By providing patients, physicians, hospitals, and policy makers with information about hospital-level, riskstandardized readmission rates following hospitalization for COPD, COPD readmission is a priority area for outcomes measure development, as it is an outcome that is likely attributable to care processes and is an important outcome for patients. Measuring and reporting readmission rates will inform healthcare providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. The measure will also provide patients with information that could guide their choices, as well as increase transparency for consumers.

S.4. Numerator Statement: The outcome for this measure is 30-day readmission. We define readmission as an inpatient admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index admission for patients discharged from the hospital with a principal discharge diagnosis of COPD or principal discharge diagnosis of respiratory failure with a secondary discharge diagnosis of acute exacerbation of COPD. If a patient has more than one unplanned admission (for any reason) within 30 days after discharge from the index admission, only the first one is counted as a readmission. The measure looks for a dichotomous yes or no outcome of whether each admitted patient has an unplanned readmission within 30 days. However, if the first readmission after discharge is considered planned, any subsequent unplanned readmission is not counted as an outcome for that index admission because the unplanned readmission could be related to care provided during the intervening planned readmission rather than during the index admission.

S.6. Denominator Statement: The cohort includes admissions for patients aged 65 or older, who have been discharged from the hospital with either a principal discharge diagnosis of COPD OR a principal discharge

diagnosis of respiratory failure with a secondary discharge diagnosis of acute exacerbation of COPD and with a complete claims history for the 12 months prior to admission.

Additional details are provided in S.9 Denominator Details.

S.8. Denominator Exclusions: The 30-day COPD readmission measures exclude index admissions for patients:

- 1. Without at least 30 days post-discharge enrollment in FFS Medicare (in the case of patients who are not VA beneficiaries);
- 2. Discharged against medical advice (AMA); and,
- 3. Admitted within 30 days of a prior index admission for COPD.
- De.1. Measure Type: Outcome
- S.17. Data Source: Claims, Enrollment Data, Other

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Mar 06, 2013 Most Recent Endorsement Date: Dec 09, 2016

IF this measure is included in a composite, NQF Composite#/title:

IF this measure is paired/grouped, NQF#/title:

De.4. IF PAIRED/GROUPED, what is the reason this measure must be reported with other measures to appropriately interpret results? This measure is paired with a measure of hospital-level 30-day, all-cause, risk-standardized mortality (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization.

1. Evidence and Performance Gap – Importance to Measure and Report

Extent to which the specific measure focus is evidence-based, important to making significant gains in healthcare quality, and improving health outcomes for a specific high-priority (high-impact) aspect of healthcare where there is variation in or overall less-than-optimal performance. *Measures must be judged to meet all sub criteria to pass this criterion and be evaluated against the remaining criteria.*

1a. Evidence to Support the Measure Focus – See attached Evidence Submission Form

NQF_evidence_COPDreadmission_Fall2020_final_7.22.20.docx

1a.1 *For Maintenance of Endorsement:* Is there new evidence about the measure since the last update/submission?

Do not remove any existing information. If there have been any changes to evidence, the Committee will consider the new evidence. Please use the most current version of the evidence attachment (v7.1). Please use red font to indicate updated evidence.

Yes

1a. Evidence (subcriterion 1a)

Measure Number (if previously endorsed): 1891

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

IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:

Date of Submission: 11/2/2020

1a.1. This is a measure of: (should be consistent with type of measure entered in De.1)

Outcome

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

□ Patient-reported outcome (PRO):

PROs include HRQoL/functional status, symptom/symptom burden, experience with care, healthrelated behaviors. (A PRO-based performance measure is not a survey instrument. Data may be collected using a survey instrument to construct a PRO measure.)

□ Intermediate clinical outcome (*e.g., lab value*):

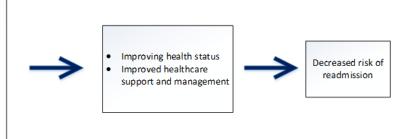
Process:

Appropriate use measure:

- □ Structure:
- Composite:
- 1a.2 LOGIC MODEL Diagram or briefly describe the steps between the healthcare structures and processes (e.g., interventions, or services) and the patient's health outcome(s). The relationships in the diagram should be easily understood by general, non-technical audiences. Indicate the structure, process or outcome being measured.

Figure 1: COPD Readmission Logic Model

- Delivery of timely, high-quality care
- Reducing the risk of infection and other complications
- Ensuring the patient is ready for discharge
- Improving communication among providers involved at care transition
- Reconciling medications
 Educating patients about symptoms, whom to contact
- with questions, and where/ when to seek follow-up careEncouraging strategies that
- promote disease management



The goal of this measure is to improve patient outcomes by providing patients, physicians, and hospitals with information about hospital-level, risk-standardized readmission rates following hospitalization for COPD. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This readmission measure was developed to identify institutions, whose performance is better or worse than would be expected based on their patient case-mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

1a.3 Value and Meaningfulness: IF this measure is derived from patient report, provide evidence that the target population values the measured *outcome, process, or structure* and finds it meaningful. (Describe how and from whom their input was obtained.)

N/A. This measure is not an intermediate outcome, process, or structure performance measure.

**RESPOND TO ONLY ONE SECTION BELOW -EITHER 1a.2, 1a.3 or 1a.4) **

1a.2 FOR OUTCOME MEASURES including PATIENT REPORTED OUTCOMES - Provide empirical data demonstrating the relationship between the outcome (or PRO) to at least one healthcare structure, process, intervention, or service.

In 2007 the Medicare Payment Advisory Committee (MedPAC) published a report to Congress in which it identified the seven conditions associated with the most costly potentially preventable readmissions. Among these seven, COPD ranked fourth (MedPAC, 2007). COPD is a leading cause of readmissions to the hospital (Jencks et al., 2009), accounting for more than 77,000 readmissions among Medicare patients and costing more than 900 million dollars a year (Hines et al., 2014). Some estimated project total costs of COPD treatment to increase to almost \$50 billion dollars by 2020, primarily driven by disease complexity, lengthy hospital admissions, and increased prevalence of comorbid conditions (Lin et al., 2020; Guarascio et al., 2013; Huber et al., 2015). Readmission rates following COPD discharge are high and variable across hospitals; for the time period of July 2015-June 2018, publicly reported 30-day risk-standardized readmission rates ranged from 15.8% to 26.1% for patients admitted with COPD (Wallace et al., 2019).

Although many current hospital interventions are known to decrease the risk of readmission within 30 days of hospital discharge (Leppin et al., 2014; Benbassat et al., 2000; Naylor et al., 1999; Coleman et al., 2006; Agee et al., 2017; Goto et al., 2018; Rezaee et al., 2018; Wright et al., 2019), current process-based performance measures, cannot capture all the ways that care within the hospital might influence outcomes. Measurement of patient outcomes allows for a comprehensive view of quality of care that reflects complex aspects of care, such as communication between providers and coordinated transitions to the outpatient environment. These aspects are critical to patient outcomes, and are broader than what can be captured by individual process-of-care measures.

The COPD hospital-specific, risk-standardized readmission rate (RSRR) measure is thus intended to inform quality-of-care improvement efforts, as individual process-based performance measures cannot encompass all the complex and critical aspects of care within a hospital that contribute to patient outcomes. As a result, many stakeholders, including patient organizations, are interested in outcomes measures that allow patients and providers to assess relative outcomes performance for hospitals (Krumholz et al., 2007). Improvement in inpatient care and care transitions for this common, costly condition are likely to reduce costly readmissions.

The diagram above indicates some of the many care processes that can influence readmission risk by improving health status or improving healthcare management and support. Early experience with care bundles suggests that that appropriate (guideline recommended care), high-quality, and timely treatment for COPD patients can reduce the risk of readmission within 30 days of hospital discharge (Hopkinson et al., 2012). Studies of integrated care management after hospitals discharge have suggested clinical benefit (Casas et al., 2006; Prieto-Centurion et al., 2014). For instance, Wake Forest Baptist Medical Center showed promising reductions in readmissions after implementing a comprehensive care plan focused on transitions of care, treatment of comorbidities, and appropriate and timely hospice and palliative care services for COPD patients (Ohar et al., 2018). Recent evidence of declining readmission rates provides further support for the concept that efforts to improve transitional care can affect a patient's risk of readmission.

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Wright EA, Graham JH, Maeng D, et al. Reductions in 30-day readmission, mortality, and costs with inpatient-to-community pharmacist follow-up. *J Am Pharm Assoc (2003)*. 2019;59(2):178-186.

1a.3. SYSTEMATIC REVIEW (SR) OF THE EVIDENCE (for INTERMEDIATE OUTCOME, PROCESS, OR STRUCTURE PERFORMANCE MEASURES, INCLUDING THOSE THAT ARE INSTRUMENT-BASED) If the evidence is not based on a systematic review go to section 1a.4) If you wish to include more than one systematic review, add additional tables.

What is the source of the *systematic review of the body of evidence* that supports the performance measure? A systematic review is a scientific investigation that focuses on a specific question and uses explicit, prespecified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may include a quantitative synthesis (meta-analysis), depending on the available data. (IOM)

□ Clinical Practice Guideline recommendation (with evidence review)

US Preventive Services Task Force Recommendation

□ Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*)

Other	r
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Systematic Review	Evidence
Source of Systematic Review: Title Author Date Citation, including page number URL 	*
Quote the guideline or recommendation verbatim about the process, structure or intermediate outcome being measured. If not a guideline, summarize the conclusions from the SR.	*
Grade assigned to the evidence associated with the recommendation with the definition of the grade	*
Provide all other grades and definitions from the evidence grading system	*
Grade assigned to the recommendation with definition of the grade	*
Provide all other grades and definitions from the recommendation grading system	*
 Body of evidence: Quantity – how many studies? Quality – what type of studies? 	*
Estimates of benefit and consistency across studies	*
What harms were identified?	*

Systematic Review	Evidence
Identify any new studies conducted since the SR. Do the new studies change the conclusions from the SR?	*

*cell intentionally left blank

1a.4 OTHER SOURCE OF EVIDENCE

If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.

N/A

1a.4.1 Briefly SYNTHESIZE the evidence that supports the measure. A list of references without a summary is not acceptable.

N/A

1a.4.2 What process was used to identify the evidence?

N/A

1a.4.3. Provide the citation(s) for the evidence.

N/A

1b. Performance Gap

Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating:

- considerable variation, or overall less-than-optimal performance, in the quality of care across providers; and/or
- Disparities in care across population groups.

1b.1. Briefly explain the rationale for this measure (e.g., how the measure will improve the quality of care, the benefits or improvements in quality envisioned by use of this measure)

If a COMPOSITE (e.g., combination of component measure scores, all-or-none, any-or-none), SKIP this question and answer the composite questions.

The goal of this measure is to improve patient outcomes. Measurement of patient outcomes allows for a broad view of quality of care that encompasses more than what can be captured by individual process-of-care measures. Readmissions following COPD are influenced by complex and critical aspects of care, such as communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient environment; several studies have demonstrated that appropriate, timely, and high-quality treatment can contribute to patient outcomes but are difficult to measure by individual process measures. The goal of outcomes measurement is to risk-adjust for patients' conditions at the time of hospital admission and then evaluate patient outcomes. This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

By providing patients, physicians, hospitals, and policy makers with information about hospital-level, riskstandardized readmission rates following hospitalization for COPD, COPD readmission is a priority area for outcomes measure development, as it is an outcome that is likely attributable to care processes and is an important outcome for patients. Measuring and reporting readmission rates will inform healthcare providers and facilities about opportunities to improve care, strengthen incentives for quality improvement, and ultimately improve the quality of care received by Medicare patients. The measure will also provide patients with information that could guide their choices, as well as increase transparency for consumers. **1b.2.** Provide performance scores on the measure as specified (*current and over time*) at the specified level of analysis. (*This is required for maintenance of endorsement*. Include mean, std dev, min, max, interquartile range, scores by decile. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities include.) This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Variation in readmission rates indicates opportunity for improvement. We conducted analyses using data from July 1, 2016 to June 30, 2019 Medicare claims and VA administrative data (n= 825,497 admissions from 4,643 hospitals).

The three-year hospital-level risk standardized readmission rates (RSRRs) have a mean of 19.6% and range from 15.5-26.8% in the study cohort. As shown below, the median risk-standardized rate is 19.6%. The distribution of RSRRs across hospitals is shown below:

Distribution of Hospital COPD RSRRs over Different Time Periods

Results for each data year

```
Characteristic//07/2016-06/2017//07/2017-06/2018//07/2018-06/2019//07/2016-06/2019
```

Number of Hospitals// 4,527 // 4,519 // 4,457 // 4,643

Number of Admissions// 322,665 // 274,391 // 228,441 // 825,497

Mean (SD) // 19.6 (0.7) // 19.6 (0.7) // 19.7 (0.8) // 19.6 (1)

Range (Min-Max)// 17-24.4 // 16.7-23.7 // 16.3-25.6 // 15.5-26.8

Minimum//17.0//16.7//16.3//15.5

```
10th percentile//18.8//18.8//18.9//18.5
```

```
20th percentile//19.1//19.1//19.2//18.9
```

30th percentile//19.3//19.3//19.4//19.2

40th percentile//19.4//19.5//19.5//19.4

50th percentile//19.5//19.6//19.6//19.6

60th percentile//19.6//19.7//19.8//19.7

70th percentile//19.8//19.9//19.9//19.9

80th percentile//20.0//20.1//20.2//20.3

90th percentile//20.4//20.4//20.6//20.8

Maximum//24.4//23.7//25.6//26.8

1b.3. If no or limited performance data on the measure as specified is reported in 1b2, then provide a summary of data from the literature that indicates opportunity for improvement or overall less than optimal performance on the specific focus of measurement.

N/A

1b.4. Provide disparities data from the measure as specified (current and over time) by population group, e.g., by race/ethnicity, gender, age, insurance status, socioeconomic status, and/or disability. (*This is required for maintenance of endorsement*. Describe the data source including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included.) For measures that show high levels of performance, i.e., "topped out", disparities data may demonstrate an opportunity for improvement/gap in care for certain sub-populations. This information also will be used to address the sub-criterion on improvement (4b1) under Usability and Use.

Distribution of 30-day COPD RSRRs by Proportion of Dual-Eligible Patients:

Data Source: Medicare FFS claims, VA data, and Medical Beneficiary Summary File (MBSF) data Dates of Data: July 2016 through June 2019 Variation in RSRRs across hospitals (with at least 25 cases) by proportion of patients with social risk// Description of Social Risk Variable//Dual-Eligibility Quartile//Q1//Q4 Social Risk Proportion (%)//(0-9.88)//(37.29-100) # of Hospitals//936//935 100%Max//25.5//24.7 90%//20.7//21.1 75%//20.1//20.4 50%//19.5//19.6 25%//19.0//19.1 10%//18.4//18.7 0%Min//16.6//15.5 Distribution of 30-day COPD RSRRs by Proportion of Patients with AHRQ SES Index Scores: Data Source: Medicare FFS claims, VA data, and The American Community Survey (2013-2017) data Dates of Data: July 2016 through June 2019 Variation in RSRRs across hospitals (with at least 25 cases) by proportion of patients in lower and upper social risk quartiles// Description of Social Risk Variable //AHRQ SES Index Quartile//Q1//Q4 Social Risk Proportion (%)//(0-12.73)//(28.63-98.75) # of Hospitals//939//925 100%Max//26.8//24.4 90%//20.8//21.1 75%//20.1//20.4 50%//19.5//19.7 25%//18.9//19.1 10%//18.4//18.6 0%Min//16.5//15.5

1b.5. If no or limited data on disparities from the measure as specified is reported in 1b.4, then provide a summary of data from the literature that addresses disparities in care on the specific focus of measurement. Include citations. Not necessary if performance data provided in 1b.4

N/A

2. Reliability and Validity—Scientific Acceptability of Measure Properties

Extent to which the measure, **as specified**, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. *Measures must be judged to meet the sub criteria for both reliability and validity to pass this criterion and be evaluated against the remaining criteria.*

2a.1. Specifications The measure is well defined and precisely specified so it can be implemented consistently within and across organizations and allows for comparability. eMeasures should be specified in the Health Quality Measures Format (HQMF) and the Quality Data Model (QDM).

De.5. Subject/Topic Area (check all the areas that apply):

Respiratory, Respiratory : Chronic Obstructive Pulmonary Disease (COPD), Respiratory : Dyspnea

De.6. Non-Condition Specific(check all the areas that apply):

Care Coordination, Care Coordination : Readmissions, Safety, Safety : Complications

De.7. Target Population Category (Check all the populations for which the measure is specified and tested if any):

Elderly, Populations at Risk

S.1. Measure-specific Web Page (Provide a URL link to a web page specific for this measure that contains current detailed specifications including code lists, risk model details, and supplemental materials. Do not enter a URL linking to a home page or to general information.)

https://www.qualitynet.org/inpatient/measures/readmission/methodology

S.2a. *If this is an eMeasure*, HQMF specifications must be attached. Attach the zipped output from the eMeasure authoring tool (MAT) - if the MAT was not used, contact staff. (Use the specification fields in this online form for the plain-language description of the specifications)

This is not an eMeasure Attachment:

S.2b. Data Dictionary, Code Table, or Value Sets (and risk model codes and coefficients when applicable) must be attached. (Excel or csv file in the suggested format preferred - if not, contact staff)

Attachment: NQF_datadictionary_COPDreadmission_Fall2020_final_7.22.20.xlsx

S.2c. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

No, this is not an instrument-based measure Attachment:

S.2d. Is this an instrument-based measure (i.e., data collected via instruments, surveys, tools, questionnaires, scales, etc.)? Attach copy of instrument if available.

Not an instrument-based measure

S.3.1. For maintenance of endorsement: Are there changes to the specifications since the last updates/submission. If yes, update the specifications for S1-2 and S4-22 and explain reasons for the changes in S3.2.

No

S.3.2. *For maintenance of endorsement,* please briefly describe any important changes to the measure specifications since last measure update and explain the reasons.

Updates consisted of updating the specifications to include new and modified ICD-10 CM/PCS codes.

S.4. Numerator Statement (Brief, narrative description of the measure focus or what is being measured about the target population, i.e., cases from the target population with the target process, condition, event, or outcome) DO NOT include the rationale for the measure.

IF an OUTCOME MEASURE, state the outcome being measured. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S. 14).

The outcome for this measure is 30-day readmission. We define readmission as an inpatient admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index admission for patients discharged from the hospital with a principal discharge diagnosis of COPD or principal discharge diagnosis of respiratory failure with a secondary discharge diagnosis of acute exacerbation of COPD. If a patient has more than one unplanned admission (for any reason) within 30 days after discharge from the index admission, only the first one is counted as a readmission. The measure looks for a dichotomous yes or no outcome of whether each admitted patient has an unplanned readmission within 30 days. However, if the first readmission after discharge is considered planned, any subsequent unplanned readmission is not

counted as an outcome for that index admission because the unplanned readmission could be related to care provided during the intervening planned readmission rather than during the index admission.

S.5. Numerator Details (All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b)

IF an OUTCOME MEASURE, describe how the observed outcome is identified/counted. Calculation of the riskadjusted outcome should be described in the calculation algorithm (S. 14).

The measure counts readmissions to any acute care hospital for any cause within 30 days of the date of discharge of the index COPD admission, excluding planned readmissions as defined below.

Planned Readmission Algorithm (Version 4.0)

The planned readmission algorithm is a set of criteria for classifying readmissions as planned using Medicare and VA administrative claims data. The algorithm identifies admissions that are typically planned and may occur within 30 days of discharge from the hospital.

The planned readmission algorithm has three fundamental principles:

- 1. A few specific, limited types of care are always considered planned (transplant surgery, maintenance chemotherapy/ immunotherapy, rehabilitation);
- 2. Otherwise, a planned readmission is defined as a non-acute readmission for a scheduled procedure; and,
- 3. Admissions for acute illness or for complications of care are never planned.

The algorithm was developed in 2011 as part of the Hospital-Wide Readmission measure. In 2013, CMS applied the algorithm to its other readmission measures.

In applying the algorithm to condition- and procedure-specific measures, teams of clinical experts reviewed the algorithm in the context of each measure-specific patient cohort and, where clinically indicated, adapted the content of the algorithm to better reflect the likely clinical experience of each measure's patient cohort. The planned readmission algorithm is applied to the COPD measure without modifications.

The planned readmission algorithm and associated code tables are attached in data field S.2b (Data Dictionary or Code Table).

S.6. Denominator Statement (Brief, narrative description of the target population being measured)

The cohort includes admissions for patients aged 65 or older, who have been discharged from the hospital with either a principal discharge diagnosis of COPD OR a principal discharge diagnosis of respiratory failure with a secondary discharge diagnosis of acute exacerbation of COPD and with a complete claims history for the 12 months prior to admission.

Additional details are provided in S.9 Denominator Details.

S.7. Denominator Details (All information required to identify and calculate the target population/denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

IF an OUTCOME MEASURE, describe how the target population is identified. Calculation of the risk-adjusted outcome should be described in the calculation algorithm (S.14).

To be included in the measure cohort used in public reporting, patients must meet the following inclusion criteria:

1. Principal discharge diagnosis of COPD or principal discharge diagnosis of respiratory failure with a secondary discharge diagnosis of COPD with exacerbation;

- 2. Enrolled in Medicare fee-for-service (FFS) in Part A and Part B Medicare for the 12 months prior to the date of admission, and enrolled in Part A during the index admission, or those who are VA beneficiaries;
- 3. Aged 65 or over;
- 4. Discharged alive from a non-federal short-term acute care hospital or VA hospital; and,
- 5. Not transferred to another acute care facility.

S.8. Denominator Exclusions (Brief narrative description of exclusions from the target population)

The 30-day COPD readmission measures exclude index admissions for patients:

- 1. Without at least 30 days post-discharge enrollment in FFS Medicare (in the case of patients who are not VA beneficiaries);
- 2. Discharged against medical advice (AMA); and,
- 3. Admitted within 30 days of a prior index admission for COPD.

S.9. Denominator Exclusion Details (All information required to identify and calculate exclusions from the denominator such as definitions, time period for data collection, specific data collection items/responses, code/value sets – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format at S.2b.)

1. Without at least 30 days of post-discharge enrollment in Medicare FFS (in the case of patients who are not VA beneficiaries), which is identified with enrollment data from the Medicare Enrollment Database.

Rationale: The 30-day readmission outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted.

2. Discharges against medical advice (AMA) are identified using the discharge disposition indicator in claims data.

Rationale: Providers did not have the opportunity to deliver full care and prepare the patient for discharge.

3. COPD admissions within 30 days of discharge from a qualifying COPD index admission are identified by comparing the discharge date from the index admission with subsequent admission dates.

Rationale: Additional COPD admissions within 30 days are excluded as index admissions because they are part of the outcome. A single admission does not count as both an index admission and a readmission for another index admission.

S.10. Stratification Information (Provide all information required to stratify the measure results, if necessary, including the stratification variables, definitions, specific data collection items/responses, code/value sets, and the risk-model covariates and coefficients for the clinically-adjusted version of the measure when appropriate – Note: lists of individual codes with descriptors that exceed 1 page should be provided in an Excel or csv file in required format with at S.2b.)

N/A

S.11. Risk Adjustment Type (Select type. Provide specifications for risk stratification in measure testing attachment)

Statistical risk model

If other:

S.12. Type of score:

Rate/proportion

If other:

S.13. Interpretation of Score (Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)

Better quality = Lower score

S.14. Calculation Algorithm/Measure Logic (*Diagram or describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; time period for data, aggregating data; risk adjustment; etc.*)

The measure estimates hospital-level 30-day, all-cause, RSRRs following hospitalization for COPD using hierarchical logistic regression models. In brief, the approach simultaneously models data at the patient and hospital levels to account for variance in patient outcomes within and between hospitals (Normand and Shahian, 2007). At the patient level, it models the log-odds of readmission within 30 days of discharge from the index admission using age, selected clinical covariates, and a hospital-specific intercept. At the hospital level, it models the hospital-specific intercepts as arising from a normal distribution. The hospital intercept represents the underlying risk of a readmission at the hospital, after accounting for patient risk. The hospital-specific intercepts are given a distribution 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 at a given hospital, multiplied by the national observed readmission rate. For each hospital, the numerator of the ratio 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 is the number of readmissions expected based on 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 rates or better quality, and a higher ratio indicates higher-than-expected readmission rates or worse quality.

The "predicted" number of readmissions (the numerator) is calculated by using the coefficients estimated by regressing the risk factors and the hospital-specific intercept on the risk of readmission. The estimated hospital-specific intercept is added to the sum of the estimated regression coefficients multiplied by the patient characteristics. The results are transformed and summed over all patients attributed to a hospital to get a predicted value. The "expected" number of readmissions (the denominator) is obtained in the same manner, but a common intercept using all hospitals in our sample is added in place of the hospital-specific intercept. The results are transformed and summed over all patients in the hospital to get an expected value. To assess hospital performance for each reporting period, we re-estimate the model coefficients using the years of data in that period.

This calculation transforms the ratio of predicted over expected into a rate that is compared to the national observed readmission rate. The hierarchical logistic regression models are described fully in the original methodology report posted on QualityNet

(https://qualitynet.org/inpatient/measures/readmission/methodology).

References:

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

S.15. Sampling (If measure is based on a sample, provide instructions for obtaining the sample and guidance on minimum sample size.)

IF an instrument-based performance measure (e.g., PRO-PM), identify whether (and how) proxy responses are allowed.

N/A. This measure is not based on a sample or survey.

S.16. Survey/Patient-reported data (*If measure is based on a survey or instrument, provide instructions for data collection and guidance on minimum response rate.*)

Specify calculation of response rates to be reported with performance measure results.

N/A

S.17. Data Source (Check ONLY the sources for which the measure is SPECIFIED AND TESTED).

If other, please describe in S.18.

Claims, Enrollment Data, Other

S.18. Data Source or Collection Instrument (Identify the specific data source/data collection instrument (e.g. name of database, clinical registry, collection instrument, etc., and describe how data are collected.)

IF instrument-based, identify the specific instrument(s) and standard methods, modes, and languages of administration.

Data sources for the Medicare FFS measure:

Medicare Part A Inpatient and Part B Outpatient Claims: This data source contains claims data for FFS inpatient and outpatient services including Medicare inpatient hospital care, outpatient hospital services, as well as inpatient and outpatient physician claims for the 12 months prior to an index admission.

Medicare Enrollment Database (EDB): This database contains Medicare beneficiary demographic, benefit/coverage, and vital status information. This data source was used to obtain information on several inclusion/exclusion indicators such as Medicare status on admission as well as vital status. These data have previously been shown to accurately reflect patient vital status (Fleming et al., 1992). The Master Beneficiary Summary File (MBSF) is an annually created file derived the EDB that contains enrollment information for all Medicare beneficiaries including dual-eligible status. Years 2016-2019 were used.

Veterans Health Administration (VA) Data: This data source contains data for VA inpatient and outpatient services including: inpatient hospital care, outpatient hospital services, skilled nursing facility care, some home health agency services, as well as inpatient and outpatient physician data for the 12 months prior to and including each index admission. Unlike Medicare FFS patients, VA patients are not required to have been enrolled in Part A and Part B Medicare for the 12 months prior to the date of admission.

The American Community Survey (2013-2017): We used the American Community Survey (2013-2017) to derive an updated AHRQSES index score at the patient nine-digit zip code level for use in studying the association between our measure and SRFs.

References

Fleming C., Fisher ES, Chang CH, Bubolz D, Malenda J. Studying outcomes and hospital utilization in the elderly: The advantages of a merged data base for Medicare and Veterans Affairs Hospitals. Medical Care. 1992; 30(5): 377-91.

S.19. Data Source or Collection Instrument (available at measure-specific Web page URL identified in S.1 OR in attached appendix at A.1)

No data collection instrument provided

S.20. Level of Analysis (Check ONLY the levels of analysis for which the measure is SPECIFIED AND TESTED)

Facility

S.21. Care Setting (Check ONLY the settings for which the measure is SPECIFIED AND TESTED)

Inpatient/Hospital

If other:

S.22. *COMPOSITE Performance Measure* - Additional Specifications (*Use this section as needed for aggregation and weighting rules, or calculation of individual performance measures if not individually endorsed.*)

N/A

2. Validity – See attached Measure Testing Submission Form

NQF_testing_COPDreadmission_Fall2020_final_11.02.20-637419148568104112.docx

2.1 For maintenance of endorsement

Reliability testing: If testing of reliability of the measure score was not presented in prior submission(s), has reliability testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.2 For maintenance of endorsement

Has additional empirical validity testing of the measure score been conducted? If yes, please provide results in the Testing attachment. Please use the most current version of the testing attachment (v7.1). Include information on all testing conducted (prior testing as well as any new testing); use red font to indicate updated testing.

Yes

2.3 For maintenance of endorsement

Risk adjustment: For outcome, resource use, cost, and some process measures, risk-adjustment that includes social risk factors is not prohibited at present. Please update sections 1.8, 2a2, 2b1,2b4.3 and 2b5 in the Testing attachment and S.140 and S.11 in the online submission form. NOTE: These sections must be updated even if social risk factors are not included in the risk-adjustment strategy. You MUST use the most current version of the Testing Attachment (v7.1) -- older versions of the form will not have all required questions.

Yes - Updated information is included

Measure Testing (subcriteria 2a2, 2b1-2b6)

Measure Number (if previously endorsed): 1891

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

Date of Submission: 11/3/2020

Type of Measure:

Measure	Measure (continued)
Outcome (<i>including PRO-PM</i>)	□ Composite – STOP – use composite testing form
🗆 Intermediate Clinical Outcome	Cost/resource
Process (including Appropriate Use)	Efficiency
□ Structure	*

*cell intentionally left blank

1. DATA/SAMPLE USED FOR ALL TESTING OF THIS MEASURE

Often the same data are used for all aspects of measure testing. In an effort to eliminate duplication, the first five questions apply to all measure testing. **If there are differences by aspect of testing**, (e.g., reliability vs. validity) be sure to indicate the specific differences in question 1.7.

1.1. What type of data was used for testing? (Check all the sources of data identified in the measure specifications and data used for testing the measure. Testing must be provided for **all** the sources of data specified and intended for measure implementation. **If different data sources are used for the numerator and denominator, indicate N [numerator] or D [denominator] after the checkbox.)**

Measure Specified to Use Data From: (must be consistent with data sources entered in S.17)	Measure Tested with Data From:
□ abstracted from paper record	□ abstracted from paper record
⊠ claims	🖾 claims
	□ registry
□ abstracted from electronic health record	\Box abstracted from electronic health record
eMeasure (HQMF) implemented in EHRs	eMeasure (HQMF) implemented in EHRs
☑ other: Medicare Enrollment Data, VHA Administrative Data	☑ other: Census Data/American Community Survey, VHA Administrative Data, Master Beneficiary Summary File

1.2. If an existing dataset was used, identify the specific dataset (the dataset used for testing must be consistent with the measure specifications for target population and healthcare entities being measured; e.g., Medicare Part A claims, Medicaid claims, other commercial insurance, nursing home MDS, home health OASIS, clinical registry).

The datasets used for testing included Medicare Parts A and B claims as well as the Medicare Enrollment Database (EDB). Additionally, census as well as enrollment data were used to assess socioeconomic factors (dual-eligible variable obtained through enrollment data; Agency for Healthcare Research and Quality [AHRQ] socioeconomic status [SES] index obtained through census data). Veterans' Health Administration (VHA) data are also included in the testing dataset. The dataset used varies by testing type; see Section 1.7 for details.

1.3. What are the dates of the data used in testing? The dates used for testing vary by testing type; see Section 1.7 for details.

1.4. What levels of analysis were tested? (*testing must be provided for all the levels specified and intended for measure implementation, e.g., individual clinician, hospital, health plan*)

Measure Specified to Measure Performance of: (must be consistent with levels entered in item S.20)	Measure Tested at Level of:
individual clinician	individual clinician
□ group/practice	□ group/practice
⊠ hospital/facility/agency	⊠ hospital/facility/agency
\Box health plan	\Box health plan
□ other:	\Box other:

1.5. How many and which *measured entities* were included in the testing and analysis (by level of analysis and data source)? (identify the number and descriptive characteristics of measured entities included in the analysis (e.g., size, location, type); if a sample was used, describe how entities were selected for inclusion in the sample)

For this measure, hospitals are the measured entities. All non-federal, short-term acute care inpatient US hospitals (including territories) with Medicare fee-for-service (FFS) beneficiaries aged 65 years or over are included. In addition, for the testing period presented, VHA hospitals and their 65 years and older patients are included in the measure. The number of measured entities (hospitals) varies by testing type; see Section 1.7 for details.

1.6. How many and which *patients* were included in the testing and analysis (by level of analysis and data

source)? (identify the number and descriptive characteristics of patients included in the analysis (e.g., age, sex, race, diagnosis); if a sample was used, describe how patients were selected for inclusion in the sample)

The number of admissions/patients varies by testing type; see Section 1.7 for details.

1.7. If there are differences in the data or sample used for different aspects of testing (e.g., reliability, validity, exclusions, risk adjustment), identify how the data or sample are different for each aspect of testing reported below.

The datasets, dates, number of measured hospitals, and number of admissions used in each type of testing are in Table 1.

Measure Development and Testing

For measure development, we used Medicare administrative claims data (2008). The dataset also included administrative data on each patient for the 12 months prior to the index admission and the 30 days following it. The dataset contained inpatient and facility outpatient claims and Medicare enrollment database (EDB) data. We randomly split the data (2008) into two equal samples: the **Development Dataset** and **Internal Validation Dataset**.

Measure Updates

For analytical updates for this measure, we used three-years of Medicare administrative claims data (July 2016 – June 2019). The dataset also included administrative data on each patient for the 12 months prior to the index admission and the 30 days following it. The dataset contained inpatient and facility outpatient claims and Medicare enrollment database (EDB) data. The dataset also included administrative data from the VHA as these hospitals are currently publicly reported for this measure.

Table 1. Dataset Descriptions

Dataset	Applicable Section in the Testing Attachment	Description of Dataset
Development and Validation Datasets (Medicare Fee-For-Service	Section 2b3 Risk Adjustment/Stratification	Entire Cohort: Dates of Data: 2008
Administrative Claims Data)	2b3.6. Statistical Risk Model Discrimination Statistics 2b3.7. Statistical Risk Model	Number of admissions = 352,631 Patient Descriptive Characteristics:
	Calibration Statistics	Number of measured hospitals: 4,553
		This cohort was randomly split for initial model testing.
		First half of split sampleNumber of Admissions: 176,480
		 Number of measured hospitals: 4,546
		Second half of split sampleNumber of Admissions: 176,151
		- Number of measured hospitals: 4,553
Testing Dataset (Medicare Fee-For-Service	Section 2a2 Reliability Testing Section 2b1 Validity Testing	Dates of Data: July 2016 – June 2019
Administrative Claims Data	Section 2b2 Testing of Measure Exclusion	Number of admissions = 825,497
	Section 2b3 Risk Adjustment/Stratification	Patient Descriptive Characteristics: Mean age = 76.6 years; % male = 44.1
	2b3.6. Statistical Risk Model Discrimination Statistics	Number of measured hospitals: 4,643
	Section 2b4 Meaningful Differences	

Dataset	Applicable Section in the Testing Attachment	Description of Dataset
The American Community Survey (ACS)	Section 2b3: Risk adjustment/Stratification for Outcome or Resource Use Measures	Dates of Data: 2013-2017 We used the AHRQSES index score derived from the ACS (2013-2017) to study the association between the 30-day readmission outcome and SRFs. The AHRQSES index score is based on beneficiary 9- digit zip code level of residence and incorporates 7 census variables found in the ACS.
Master Beneficiary Summary File (MBSF)	Section 2b3: Risk adjustment/Stratification for Outcome or Resource Use Measures	Dates of Data: July 2016 – June 2019 We used dual-eligible status (for Medicare and Medicaid) derived from the MBSF to study the association between the 30-day measure outcome and dual-eligible status.

1.8 What were the social risk factors that were available and analyzed? For example, patient-reported data (e.g., income, education, language), proxy variables when social risk data are not collected from each patient (e.g. census tract), or patient community characteristics (e.g. percent vacant housing, crime rate) which do not have to be a proxy for patient-level data.

We selected social risk factor (SRF) variables to analyze after reviewing the literature and examining available national data sources. We sought to find variables that are consistently captured in a reliable fashion for all patients in this measure. There is a large body of literature linking various SRFs to worse health status and higher readmissions over a lifetime. Income, education, and occupation are the most commonly examined SRFs studied. The causal pathways for SRF variable selection are described below in Section 2b3.3a. Unfortunately these variables are not available at the patient level for this measure. Therefore proxy measures of income, education level and economic status were selected.

The SRF variables used for analysis were:

• Dual-eligible status: Dual-eligible status (i.e., enrolled in both Medicare and Medicaid) patient-level data is obtained from the CMS Master Beneficiary Summary File (MBSF)

Following guidance from ASPE and a body of literature demonstrating differential health care and health outcomes among dua- eligible patients, we identified dual-eligibility as a key variable (ASPE 2016; ASPE 2020). We recognize that Medicare-Medicaid dual-eligibility has limitations as a proxy for patients' income or assets because it does not provide a range of results and is only a dichotomous outcome. However, the threshold for over 65-year-old Medicare patients is valuable, as it takes into account both income and assets and is consistently applied across states for the older population. We acknowledge that it is important to test a wider variety of SRFs including key variables such as education and poverty level; therefore, we also tested a validated composite based on census data linked to as small a geographic unit as possible.

• AHRQ-validated SES index score (summarizing the information from the following 7 variables): percentage of people in the labor force who are unemployed, percentage of people living below poverty level, median

household income, median value of owner-occupied dwellings, percentage of people \geq 25 years of age with less than a 12th grade education, percentage of people \geq 25 years of age completing \geq 4 years of college, and percentage of households that average \geq 1 people per room).

Finally, The AHRQ SES index score is a well-validated variable that describes the average SES of people living in small defined geographic areas (Bonito et al., 2008). Its value as a proxy for patient-level information is dependent on having the most granular-level data with respect to communities that patients live in. We considered the area deprivation index (ADI) among many other potential indicators when we initially evaluated the impact of SDS indicators. We ultimately did not include the ADI at the time, partly due to the fact that the coefficients used to derive ADI had not been updated for many years. Recently, the coefficients for ADI have been updated and therefore we compared the ADI with the AHRQ SES Index and found them to be highly correlated. In this submission, we present analyses using the census block level, the most granular level possible using American Community Survey (ACS) data. A census block group is a geographical unit used by the US Census Bureau which is between the census tract and the census block. It is the smallest geographical unit for which the bureau publishes sample data. The target size for block groups is 1,500 and they typically have a population of 600 to 3,000 people. We used 2013-2017 ACS data and mapped patients' 9digit ZIP codes via vendor software to the census block group level. Given the variation in cost of living across the country, the median income and median property value components of the AHRQ SES Index were adjusted by regional price parity values published by the Bureau of Economic Analysis (BEA). This provides a better marker of low SES neighborhoods in high expense geographic areas. We then calculated an AHRQ SES Index score for census block groups that can be linked to 9-digit ZIP codes. We used the percentage of patients with an AHRQSES index score equal to or below 42.7 to define the lowest quartile of the AHRQSES Index.

References:

Adler NE, Newman K. Socioeconomic disparities in health: pathways and policies. Health affairs (Project Hope). 2002; 21(2):60-76.

Blum AB, Egorova NN, Sosunov EA, et al. Impact of socioeconomic status measures on hospital profiling in New York City. Circulation. Cardiovascular quality and outcomes. May 2014; 7(3):391-397.

Bonito A, Bann C, Eicheldinger C, Carpenter L. Creation of new race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries. Final Report, Sub-Task. 2008;2.

Chen HF, Nevola A, Bird TM, et al. Understanding factors associated with readmission disparities among Delta region, Delta state, and other hospitals. Am J Manag Care May 2018.25(5): e150-156.

Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation (ASPE). Report to Congress: Social Risk factors and Performance Under Medicare's Value-based Payment Programs. 2016; <u>https://aspe.hhs.gov/pdf-report/report-congress-social-risk-factors-and-performance-under-medicares-value-based-purchasing-programs</u>. Accessed November 10, 2019.

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

Eapen ZJ, McCoy LA, Fonarow GC, Yancy CW, Miranda ML, Peterson ED, Califf RM, HernandezAF. Utility of socioeconomic status in predicting 30-day outcomes after heart failure hospitalization. Circ Heart Fail. May 2015; 8(3):473-80.

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Hu J, Gonsahn MD, Nerenz DR. Socioeconomic status and readmissions: evidence from an urban teaching hospital. Health affairs (Project Hope). 2014; 33(5):778-785.

Kaplan CM, Thompson MP, Waters TM. How Have 30-Day Readmission Penalties Affected Racial Disparities in Readmissions?: an Analysis from 2007 to 2014 in Five US States. *J Gen Intern Med.* 2019;34(6):878-883.

Khan JA, Casper M, Asimos AW, et al. Geographic and sociodemographic disparities in drive times to Joint Commission-certified primary stroke centers in North Carolina, South Carolina, and Georgia. Preventing chronic disease. Jul 2011;8(4):A79.

Mackenbach JP, Cavelaars AE, Kunst AE, Groenhof F. Socioeconomic inequalities in cardiovascular disease mortality; an international study. European heart journal. 2000; 21(14):1141-1151.

Pedigo A, Seaver W, Odoi A. Identifying unique neighborhood characteristics to guide health planning for stroke and heart attack: fuzzy cluster and discriminant analyses approaches. PloS one. 2011;6(7):e22693.

Tonne C, Schwartz J, Mittleman M, Melly S, Suh H, Goldberg R. Long-term survival after acute myocardial infarction is lower in more deprived neighborhoods. Circulation. Jun 14 2005; 111(23):3063-3070.

2a2. RELIABILITY TESTING

Note: If accuracy/correctness (validity) of data elements was empirically tested, separate reliability testing of data elements is not required – in 2a2.1 check critical data elements; in 2a2.2 enter "see section 2b2 for validity testing of data elements"; and skip 2a2.3 and 2a2.4.

2a2.1. What level of reliability testing was conducted? (may be one or both levels)

Critical data elements used in the measure (*e.g., inter-abstractor reliability; data element reliability must address ALL critical data elements*)

Performance measure score (e.g., signal-to-noise analysis)

2a2.2. For each level checked above, describe the method of reliability testing and what it tests (*describe the steps*—*do not just name a method; what type of error does it test; what statistical analysis was used*)

Measure Score Reliability

We performed two types of reliability testing. First, we estimated the overall measure score reliability by calculating the intra-class correlation coefficient (ICC) using a split sample (i.e. test-retest) method. Second, we estimated the facility-level reliability (signal-to-noise reliability).

Split-Sample Reliability

The reliability of a measurement is the degree to which repeated measurements of the same entity agree with each other. For measures of hospital performance, the measured entity is naturally the hospital, and reliability is the extent to which repeated measurements of the same hospital give similar results. Accordingly, our approach to assessing reliability is to consider the extent to which assessments of a hospital using different but randomly selected subsets of patients produce similar measures of hospital performance. That is, we take a "test-retest" approach in which hospital performance is measured once using a random subset of patients, and then measured again using a second random subset exclusive of the first, and the agreement of the two resulting performance measures compared across hospitals (Rousson, Gasser, and Seifert, 2002).

For test-retest reliability of the measure in aged 65 years and older, we randomly sampled half of patients within each hospital for a three year period, calculated the measure for each hospital, and repeated the

calculation using the second half. Thus, each hospital is measured twice, but each measurement is made using an entirely distinct set of patients. To the extent that the calculated measures of these two subsets agree, we have evidence that the measure is assessing an attribute of the hospital, not of the patients. As a metric of agreement we calculated the intra-class correlation coefficient (Shrout & Fleiss, 1979), and assessed the values according to conventional standards (Landis & Koch, 1977). Specifically, we used a combined 2016-2019 sample, randomly split it into two approximately equal subsets of patients, and calculated the RSRR for each hospital for each sample. The agreement of the two RSRRs was quantified for hospitals in each sample using the intra-class correlation as defined by ICC (2,1) (Shrout & Fleiss, 1979).

Using two non-overlapping random samples provides a conservative estimate of the measure's reliability, compared with using two random but potentially overlapping samples which would exaggerate the agreement. Moreover, because our final measure is derived using hierarchical logistic regression, and a known property of hierarchical logistic regression models is that smaller volume hospitals contribute less 'signal', a split sample using a single measurement period would introduce extra noise. This leads to an underestimate in the actual test-retest reliability that would be achieved if the measure were reported using the full measurement period, as evidenced by the Spearman Brown prophecy formula (Spearman 1910, Brown 1910). We used this formula to estimate the reliability of the measure if the whole cohort were used, based on an estimate from half the cohort.

Signal-to-Noise

We estimated the signal to noise reliability (facility-level reliability), which is the reliability with which individual units (hospitals) are measured. While test re-test reliability is the most relevant metric from the perspective of overall measure reliability, it is also meaningful to consider the separate notion of "unit" reliability, that is, the reliability with which individual units (here, hospitals) are measured. The reliability of any one facility's measure score will vary depending on the number of patients admitted for COPD. Facilities with more volume (i.e., with more patients) will tend to have more reliable scores, while facilities with less volume will tend to have less reliable scores. Therefore, we used the formula presented by Adams and colleagues (2010) to calculate facility-level reliability.

Where facility-to-facility variance is estimated from the hierarchical logistic regression model, n is equal to each facility's observed case size, and the facility error variance is estimated using the variance of the logistic distribution ($\pi^2/3$). The facility-level reliability testing is limited to facilities with at least 25 admissions for public reporting.

Signal to noise reliability scores can range from 0 to 1. A reliability of zero implies that all the variability in a measure is attributable to measurement error. A reliability of one implies that all the variability is attributable to real difference in performance.

Additional Information

In constructing the measure, we aim to utilize only those data elements from the claims that have both face validity and reliability. We avoid the use of fields that are thought to be coded inconsistently across providers. Specifically, we use fields that are consequential for payment and which are audited. We identify such variables through empiric analyses and our understanding of CMS auditing and billing policies and seek to avoid variables which do not meet this standard.

In addition, CMS has in place several hospital auditing programs used to assess overall claims code accuracy, to ensure appropriate billing, and for overpayment recoupment. CMS routinely conducts data analysis to identify potential problem areas and detect fraud, and audits important data fields used in our measures, including diagnosis and procedure codes and other elements that are consequential to payment.

Furthermore, we assessed the variation in the frequency of the variables over time: detailed information is presented in the measure's 2020 Condition-Specific Measure Updates and Specifications Report cited below.

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2a2.3. For each level of testing checked above, what were the statistical results from reliability testing? (e.g., percent agreement and kappa for the critical data elements; distribution of reliability statistics from a signal-to-noise analysis)

Measure Score Reliability Results

Split-Sample Reliability

In total, 825,497 admissions were included in the analysis, using 3 years of data. After randomly splitting the sample into two halves, there were 411,617 admissions from 4,591 hospitals in one half and 413,880 admissions from 4,643 hospitals in the other half. As a metric of agreement, we calculated the ICC for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSRR for each hospital was 0.406.

Signal-to-Noise

We calculated the signal-to-noise reliability score for each hospital with at least 25 admissions* (see Table 2 below). The median reliability score was 0.43, ranging from 0.11 to 0.90. The 25th and 75th percentiles were 0.25 and 0.60, respectively. The median reliability score demonstrates moderate reliability between the two samples.

Table 2. Signal-to-noise reliability distribution for COPD readmission

Mean	Std Dev.	Min	5 th Percentile	10 th Percentile	25 th Percentile	Median	75 th Percentile	90 th Percentile	95 th Percentile	Max
0.43	0.20	0.11	0.13	0.16	0.25	0.43	0.60	0.70	0.75	0.90

*Hospital measure scores are calculated for all hospitals (including those that have fewer than 25 admissions) but only publicly reported for those that have at least 25 admissions to ensure hospital results are reliable.

2a2.4 What is your interpretation of the results in terms of demonstrating reliability? (i.e., what do the results mean and what are the norms for the test conducted?)

Measure Score Reliability Results

The split-sample reliability score of 0.406, discussed in the previous section, represents the lower bound of estimate of the true measure reliability.

Using the approach used by Adams et. al. and Yu et al., we obtained the median signal-to-noise reliability score of 0.43, which demonstrates moderate agreement.

Our interpretation of the results is based on the standards established by Landis and Koch (1977):

- < 0 Less than chance agreement;
- 0 0.2 Slight agreement;
- 0.21-0.39 Fair agreement;
- 0.4 0.59 Moderate agreement;
- 0.6 0.79 Substantial agreement;
- 0.8-0.99 Almost Perfect agreement; and
- 1 Perfect agreement

Taken together, these results indicate that there is moderate reliability in the measure score.

In the absence of empirically supported standards, our position is that 'acceptability' depends on context. For simple concepts or constructs, such as a patient's weight, the expectation is that the test-retest reliability of a measure of that construct should be quite high. However, for complex constructs, such as clinical severity, patient comorbidity, or symptom profiles used to identify a condition or clinical state, reliability of measures used to define these constructs is quite a bit lower.

References:

Adams J, Mehrota, A, Thoman J, McGlynn, E. (2010). Physician cost profiling – reliability and risk of misclassification. NEJM, 362(11): 1014-1021.

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2b1. VALIDITY TESTING

2b1.1. What level of validity testing was conducted? (may be one or both levels)

Critical data elements (*data element validity must address ALL critical data elements*)

⊠ Performance measure score

\boxtimes Empirical validity testing

Systematic assessment of face validity of *performance measure score* as an indicator of quality or resource use (*i.e., is an accurate reflection of performance on quality or resource use and can distinguish good from poor performance*) **NOTE**: Empirical validity testing is expected at time of maintenance review; if not possible, justification is required.

2b1.2. For each level of testing checked above, describe the method of validity testing and what it tests (describe the steps—do not just name a method; what was tested, e.g., accuracy of data elements compared to authoritative source, relationship to another measure as expected; what statistical analysis was used)

Empirical Validity

Stewards of NQF-endorsed measures going through the re-endorsement process are required to demonstrate external validity testing at the time of maintenance review, or if this is not possible, justify the use of face validity only. To meet this requirement for the COPD readmission measure, we identified and assessed the measure's correlation with other measures that target the same domain of quality (e.g. complications, safety, or post-procedure utilization) for the same or similar populations. The goal was to identify if better performance in this measure was related to better performance on other relevant structural or outcomes measures. After literature review and consultations with measures experts in the field, there were very few

measures identified that assess the same domains of quality. Given that challenge, we selected the following to use for validity testing.

- Hospital Star Rating Readmission group score: CMS's Overall Hospital Star Rating assesses hospitals' overall performance (expressed on *Hospital Compare* graphically, as stars) based on a weighted average of group scores from different domains of quality (Mortality, Readmissions, Safety, Patient Experience, Imaging, Effectiveness of Care, Timeliness of Care). The Readmission group is comprised of the readmission measures that are publicly reported on *Hospital Compare*. The Readmission group score is derived from a latent variable model that identifies an underlying quality trait for that group. For the validity testing presented in this testing form, we used readmission group scores from 4,643 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Rating can be found at: <u>https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources</u>.
- 2. Overall Hospital Star Rating: CMS's Overall Hospital Star Rating assesses hospitals' overall performance (expressed on *Hospital Compare* graphically, as stars) based on a weighted average of "group scores" from different domains of quality (Mortality, Readmissions, Safety, Patient Experience, Imaging, Effectiveness of Care, Timeliness of Care). Each group has within it, measures that are reported on *Hospital Compare*. Group scores for each individual group are derived from latent variable models that identify an underlying quality trait for each group. Group scores are combined into an overall hospital score using fixed weights; overall hospital scores are then clustered, using k-means clustering, into five groups and are assigned one-to-five stars (the hospital's Star Rating). For the validity testing presented in this testing form, we used hospital's Star Ratings from 4,643 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Rating can be found at <u>https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources.</u>

We examined the relationship of performance the COPD readmission measure scores (RSRR) with each of the external measures of hospital quality. For the external measures, the comparison was against performance within quartiles of the Readmission group score, or in the case of Star Ratings, to the Star Rating category (1-5 Stars). We predicted the COPD readmission scores would be more strongly associated with the Hospital Star Rating Readmission group score than the Overall Star Ratings scores, with lower RSRRs associated with better Star Ratings.

In addition to providing empirical evidence, we have found multiple sources that support that readmissions can represent a signal of hospital quality. Readmissions have been shown to be associated with low hospital quality. Hospitals that have adopted strategies to improve care processes such as discharge planning, patient education, and transitions of care, tend to perform better on these measures (e.g. Borza et al., 2019; Cyriac et al., 2016; Jack et al., 2009; Curry et al., 2011; Bradley et al., 2013; Koehler et al., 2009; Harrison et al., 2011; Hernandez et al., 2010; Kao et al., 2016; Radhakrishnan et al. 2018; Leppin et al., 2014; Patel et al., 2018; Ohar et al., 2018; Wright et al., 2019).

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Face Validity as Determined by TEP:

One means of confirming the validity of this measure was face validity assessed by our Technical Expert Panel (TEP), which included 11 members including individuals with diverse perspectives and backgrounds, including clinicians, consumers, hospitals, purchasers, and experts in quality improvement.

List of TEP Members

- Darlene Bainbridge, MS, NHA, CPHQ, CPHRM (President/CEO, Darlene D. Bainbridge & Associates, Inc.)
- Robert A. Balk, MD (Director of Pulmonary and Critical Care Medicine, Rush University Medical Center)
- Dale Bratzler, DO, MPH (President and CEO, Oklahoma Foundation for Medical Quality)
- Scott Cerreta, RRT (Director of Education, COPD Foundation)
- Gerard J. Criner, MD (Director of Temple Lung Center and Divisions of Pulmonary and Critical Care Medicine, Temple University)
- Guy D'Andrea, MBA (President, Discern Consulting)
- Jonathan Fine, MD (Director of Pulmonary Fellowship, Research and Medical Education, Norwalk Hospital)

- David Hopkins, MS, PhD (Senior Advisor, Pacific Business Group on Health)
- Fred Martin Jacobs, MD, JD, FACP, FCCP, FCLM (Executive Vice President and Director, Saint Barnabas Quality Institute)
- Natalie Napolitano, MPH, RRT NPS (Respiratory Therapist, Inova Fairfax Hospital)
- Russell Robbins, MD, MBA (Principal and Senior Clinical Consultant, Mercer)

We systematically assessed the face validity of the measure score as an indicator of quality by soliciting the TEP members' agreement with the following statement: "The risk-standardized readmission rates obtained from the COPD readmission measure as specified will provide an accurate reflection of quality."

On a six-point scale (1=Strongly disagree, 2=Moderately disagree, 3=Somewhat disagree, 4=Somewhat agree, 5=Moderately agree, 6=Strongly agree), 10 of 11 TEP members responded to the survey question as follows: one TEP member Strongly Disagreed, two Somewhat Agreed, four Moderately Agreed, and three Strongly Agreed. Of the TEP members who responded, 90% agreed (70% moderately or strongly agreed) that the measure will provide an accurate reflection of quality. We therefore gave the measure a moderate rating for face validity. In summary, these results demonstrated TEP agreement with the overall face validity of the measure as specified.

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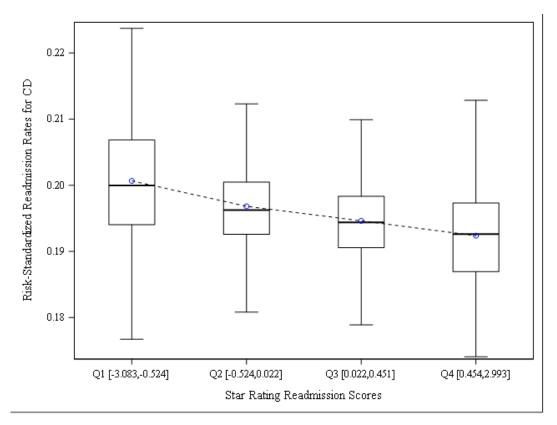
Disposition&blobheadervalue1=attachment%3Bfilename%3DRdmsn_CABG_MeasMethd_Rpt_060314.pdf&blobcol=urldata&blobtable=MungoBlobs. Accessed November 4, 2015.

2b1.3. What were the statistical results from validity testing? (e.g., correlation; t-test)

Correlation between COPD RSRRs and Star-Ratings Readmission Group Scores

Figure 1 shows the box-whisker plots of the COPD readmission measure RSRRs within each quartile of Star Rating Readmission scores. The blue circles represent the mean RSRRs of Star Rating readmission score quartiles. The correlation between COPD RSRRs and Star Rating Readmissions score is -0.442, which suggests that hospitals with lower COPD RSRRs are more likely to have higher Star Rating Readmission scores.

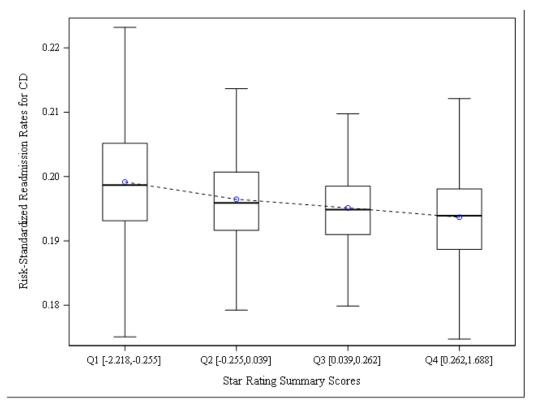
Figure 1

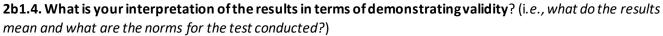


Correlation between COPD RSRRs and Overall Star-Ratings Scores

Figure 2 shows the Box-whisker plots of the COPD readmission measure RSRRs within each quartile of Star Rating summary scores. The blue circles represent the mean RSRRs of Star Rating summary score quartiles. The correlation between COPD RSRRs and Star Rating summary score is -0.286, which suggests that hospitals with lower COPD RSRRs are more likely to have higher Star Rating summary scores.

Figure 2





Empirical Validity Testing

This validation approach compares the 30-day COPD readmission measure results against the Star Rating Readmission and summary scores. Figure 1 and 2 Box Plots results demonstrate an observed trend of lower risk-standardized readmissions with higher star ratings, which supports measure score validity. The correlation coefficients associated with both the Star Ratings Readmission domain and overall star ratings with the COPD readmission measure indicate moderate associations, which is to be expected given that these measures are calculated by complex statistical models. Overall, the results above show that the trend and direction of this association is in line with what would be expected.

2b2. EXCLUSIONS ANALYSIS

NA \Box no exclusions – *skip to section* <u>2b3</u>

2b2.1. Describe the method of testing exclusions and what it tests (*describe the steps*—*do not just name a method; what was tested, e.g., whether exclusions affect overall performance scores; what statistical analysis was used*)

All exclusions were determined by careful clinical review and have been made based on clinically relevant decisions to ensure accurate calculation of the measure. To ascertain impact of exclusions on the cohort, we examined overall frequencies and proportions of the total cohort excluded for each exclusion criterion (Testing Dataset). These exclusions are consistent with similar NQF-endorsed outcome measures. Rationales for the exclusions are detailed in data field S.9 (Denominator Exclusions).

2b2.2. What were the statistical results from testing exclusions? (include overall number and percentage of individuals excluded, frequency distribution of exclusions across measured entities, and impact on performance measure scores)

In the Testing Dataset (Table 3):

	Exclusion	N	%	Distribution across hospitals (N=3,782): Min, 25 th , 50 th , 75 th , 99 th percentile, Max
1.	Discharged against medical advice (AMA)	6,926	0.77	(0.00, 0.00, 0.41, 1.08, 13.8)
2.	Without at least 30 days post- discharge enrollment in FFS Medicare for index admission	6,186	0.69	(0.00, 0.00, 0.43, 1.02, 8.33)
3.	COPD admission within 30 days of a prior COPD index admission	63,564	7.05	(0.00, 4.69, 6.45, 8.09, 24.0)

2b2.3. What is your interpretation of the results in terms of demonstrating that exclusions are needed to prevent unfair distortion of performance results? (*i.e.*, the value outweighs the burden of increased data collection and analysis. Note: If patient preference is an exclusion, the measure must be specified so that the effect on the performance score is transparent, e.g., scores with and without exclusion)

Exclusion 1 (patients who are discharged AMA) accounts for 0.77% of all index admissions excluded from the initial index cohort. This exclusion is needed for acceptability of the measure to hospitals, who do not have the opportunity to deliver full care and prepare the patient for discharge. Given that a very small percentage of patients are being excluded, it is unlikely this exclusion affects the measure score.

Exclusion 2 (patients without at least 30 days post-discharge enrollment in FFS Medicare for index admissions) accounts for 0.69% of all index admissions excluded from the initial index cohort. This exclusion is needed since the 30-day readmission outcome cannot be assessed in this group since claims data are used to determine whether a patient was readmitted.

For *Exclusion 3* (patients with admissions within 30 days of a prior index admission) if a patient has an admission within 30 days of discharge from the index admission, that admission is not included in the cohort so that admission can be both an index admission and readmission. This exclusion accounts for 7.05% of all index admissions excluded from the initial index cohort.

2b3. RISK ADJUSTMENT/STRATIFICATION FOR OUTCOME OR RESOURCE USE MEASURES

If not an intermediate or health outcome, or PRO-PM, or resource use measure, skip to section 2b4.

2b3.1. What method of controlling for differences in case mix is used?

- □ No risk adjustment or stratification
- Statistical risk model with 40 risk factors
- □ Stratification by risk categories
- □ Other,

2b3.1.1 If using a statistical risk model, provide detailed risk model specifications, including the risk model method, risk factors, coefficients, equations, codes with descriptors, and definitions.

See risk model specifications in Section 2b3.4a and the attached data dictionary.

2b3.2. If an outcome or resource use component measure is *not risk adjusted or stratified*, provide *rationale and analyses* to demonstrate that controlling for differences in patient characteristics (case mix) is not needed to achieve fair comparisons across measured entities.

N/A. This measure is risk adjusted.

2b3.3a. Describe the conceptual/clinical *and* statistical methods and criteria used to select patient factors (clinical factors or social risk factors) used in the statistical risk model or for stratification by risk (*e.g.*, *potential factors identified in the literature and/or expert panel; regression analysis; statistical significance of p<0.10; correlation of x or higher; patient factors should be present at the start of care*) Also discuss any "ordering" of risk factor inclusion; for example, are social risk factors added after all clinical factors?

Selecting Risk Variables

Our goal in selecting risk factors for adjustment was to develop parsimonious models that included clinically relevant variables strongly associated with the risk of readmission in the 30 days following an index admission. We used a two stage approach, first identifying the comorbidity or clinical status risk factors that were most important in predicting the outcome, then considering the potential addition of social risk factors.

The original measure was developed with ICD-9. When ICD-10 became effective in 2015, we transitioned the measure to use ICD-10 codes as well. ICD-10 codes were identified using 2015 GEM mapping software. We then enlisted the help of clinicians with expertise in relevant areas to select and evaluate which ICD-10 codes map to the ICD-9 codes used to define this measure during development. A code set is attached in field S.2b. (Data Dictionary).

For risk model development, we started with Condition Categories (CCs) which are part of CMS's Hierarchical Condition Categories (HCCs). The current HCC system groups the 70,000+ ICD-10-CM and 17,000+ ICD-9-CM codes into larger clinically coherent groups (201 CCs) that are used in models to predict mortality or other outcomes (Pope et al. 2001; 2011). The HCC system groups ICD codes into larger groups that are used in models to predict medical care utilization, mortality, or other related measures.

To select candidate variables, a team of clinicians reviewed all CCs and excluded those that were not relevant to the Medicare population or that were not clinically relevant to the readmission outcome (for example, attention deficit disorder, female infertility). All potentially clinically relevant CCs were included as candidate variables and, consistent with CMS's other claims-based readmission measures, some of those CCs were then combined into clinically coherent CC groupings.

To inform final variable selection, a modified approach to stepwise logistic regression was performed. The Development Sample was used to create 1,000 "bootstrap" samples. For each sample, we ran a logistic stepwise regression that included the candidate variables. The results (not shown in this report) were summarized to show the percentage of times that each of the candidate variables was significantly associated with readmission (p<0.01) in each of the 1,000 repeated samples (for example, 90 percent would mean that the candidate variable was selected as significant at p<0.01 in 90 percent of the times). We also assessed the direction and magnitude of the regression coefficients.

The clinical team reviewed these results and decided to retain risk adjustment variables above a predetermined cutoff, because they demonstrated a strong and stable association with risk of readmission and were clinically relevant. Additionally, specific variables with particular clinical relevance to the risk of readmission were forced into the model (regardless of percent selection) to ensure appropriate risk adjustment for COPD. These included variables representing markers for end of life/frailty, such as:

Markers for end of life/frailty:

- Decubitus Ulcer or Chronic Skin Ulcer (CC 157-CC 161)
- Metastatic and Other Severe Cancers (CC 8-CC 15)
- Hemiplegia, Paraplegia, Paralysis, Functional disability (CC 70-CC 74, CC 103, CC 104, CC 189-CC 190)
- Stroke (CC 99-CC 100)
- Chronic Kidney Disease, Stage 5 (CC 136)

This resulted in a final risk-adjustment model that included 40 variables.

Social Risk Factors

We weigh SRF adjustment using a comprehensive approach that evaluates the following:

- Well-supported conceptual model for influence of SRFs on measure outcome (detailed below);
- Feasibility of testing meaningful SRFs in available data (section 1.8); and
- Empiric testing of SRFs (section 2b3.4b).

Below, we summarize the findings of the literature review and conceptual pathways by which SRFs may influence risk of the outcome, as well as the statistical methods for SRF empiric testing. Our conceptualization of the pathways by which patients' social risk factors affect the outcome is informed by the literature cited below and IMPACT Act-funded work by the National Academy of Science, Engineering and Medicine (NASEM) and the Department of Health and Human Services Assistant Secretary for Policy and Evaluation (ASPE).

Causal Pathways for Social Risk Variable Selection

Although some recent literature evaluates the relationship between patient SRFs and the readmission outcome, few studies directly address causal pathways or examine the role of the hospital in these pathways (see, for example; Goto et al., 2017; Jacobs et al., 2018; Trivedi et al., 2014; Buntin et al., 2017; Hamadi et al., 2019). Moreover, the current literature examines a wide range of conditions and risk variables with no clear consensus on which risk factors demonstrate the strongest relationship with readmission.

The social risk factors that have been examined in the literature can be categorized into three domains: (1) patient-level variables, (2) neighborhood/community-level variables, and (3) hospital-level variables.

Patient-level variables describe characteristics of individual patients, and include the patient's income or education level (Eapen et al., 2015). Neighborhood/community-level variables use information from sources such as the ACS as either a proxy for individual patient-level data or to measure environmental factors. Studies using these variables use one dimensional measures such as median household income or composite measures such as the AHRQ-validated SES index score (Blum et al., 2014). Some of these variables may include the local availability of clinical providers (Herrin et al., 2015; Herrin et al., 2016). Hospital-level variables measure attributes of the hospital which may be related to patient risk. Examples of hospital-level variables used in studies are ZIP code characteristics aggregated to the hospital level or the proportion of Medicaid patients served in the hospital (Gilman et al., 2014; Joynt et al., 2013; Jha et al., 2013).

The conceptual relationship, or potential causal pathways by which these possible social risk factors influence the risk of readmission following an acute illness or major surgery, like the factors themselves, are varied and complex. There are at least four potential pathways that are important to consider:

- 1. Patients with social risk factors may have worse health at the time of hospital admission. Patients who have lower income/education/literacy or unstable housing may have a worse general health status and may present for their hospitalization or procedure with a greater severity of underlying illness. These social risk factors, which are characterized by patient-level or neighborhood/community-level (as proxy for patient-level) variables, may contribute to worse health status at admission due to competing priorities (restrictions based on job), lack of access to care (geographic, cultural, or financial), or lack of health insurance. Given that these risk factors all lead to worse general health status, this causal pathway should be largely accounted for by current clinical risk-adjustment.
- 2. Patients with social risk factors often receive care at lower quality hospitals. Patients of lower income, lower education, or unstable housing have inequitable access to high quality facilities, in part, because such facilities are less likely to be found in geographic areas with large populations of poor patients. Thus, patients with low income are more likely to be seen in lower quality hospitals, which can explain increased risk of readmission following hospitalization.

- 3. **Patients with social risk factors may receive differential care within a hospital**. The third major pathway by which social risk factors may contribute to readmission risk is that patients may not receive equivalent care within a facility. For example, patients with social risk factors such as lower education may require differentiated care (e.g. provision of lower literacy information that they do not receive).
- 4. Patients with social risk factors may experience worse health outcomes beyond the control of the health care system. Some social risk factors, such as income or wealth, may affect the likelihood of readmissions without directly affecting health status at admission or the quality of care received during the hospital stay. For instance, while a hospital may make appropriate care decisions and provide tailored care and education, a lower-income patient may have a worse outcome post-discharge due to competing financial priorities which don't allow for adequate recuperation or access to needed treatments, or a lack of access to care outside of the hospital.

Although we analytically aim to separate these pathways to the extent possible, we acknowledge that risk factors often act on multiple pathways, and as such, individual pathways are complex to distinguish analytically. Further, some social risk factors, despite having a strong conceptual relationship with worse outcomes, may not have statistically meaningful effects on the risk model. They also have different implications on the decision to risk adjust or not.

Based on this model and the considerations outlined in section 1.8 – namely, that the AHRQSES index and dual-eligibility variables aim to capture the SRFs that are likely to influence these pathways (income, education, housing, and community factors) - the following social risk variables were considered for risk-adjustment:

- Dual-eligible status
- AHRQSES index

Statistical Methods

We assessed the relationship between the SRF variables with the outcome and examined the incremental effect in a multivariable model. For this measure, we also examined the extent to which the addition of any one of these variables improved model performance or changed hospital results.

One concern with including SRFs in a model is that their effect may be at either the patient or the hospital level. For example, low SES may increase the risk of readmission because patients of low SES have an individual higher risk (patient-level effect) or because patients of low SES are more often admitted to hospitals with higher overall readmission rates (hospital-level effect). Identifying the relative contribution of the hospital level is important in considering whether a factor should be included in risk adjustment; if an effect is primarily a hospital-level effect, adjusting for it is equivalent to adjusting for differences in hospital quality. Thus, as an additional step, we assessed whether there was a "contextual effect" at the hospital level. To do this, we performed a decomposition analysis to assess the independent effects of the SRF variables at the patient level and the hospital level. If, for example, the elevated risk of readmission for patients of low SES, then a significant hospital-level effect would be expected with little-to-no patient-level effect. However, if the increased readmission risk were solely related to higher risk for patients of low SES regardless of hospital effect, then a significant patient-level effect would be expected and a significant hospital-level effect would not be expected.

Specifically, we modeled the SRF variables as follows, let X_{ij} be a binary indicator of the SRF status of the ith patient at the jth hospital, and X_j the percent of patients at hospital j with $X_{ij} = 1$. Then we added both $X_{ij} \equiv X_{patient}$ and $X_j \equiv X_{hospital}$ to the model. The first variable, $X_{patient}$, represents the effect of the risk factor at the patient level (sometimes called the "within" hospital effect), and the second variable, $X_{hospital}$, represents the effect at the hospital level (sometimes called the "between" hospital effect). By including both of these in the same model, we can assess whether these are independent effects, whether one effect dominates the other,

or whether only one of these effects contributes. This analysis allows us to simultaneously estimate the independent effects of: 1) hospitals with higher or lower proportions of low SES patients on the readmission rate of an average patient; and 2) a patient's SES on their own readmission rates when seen at an average hospital.

It is very important to note, however, that even in the presence of a significant patient-level effect and absence of a significant hospital-level effect, the increased risk could be partly or entirely due to the quality of care patients receive in the hospital. For example, biased or differential care provided within a hospital to low-income patients as compared to high-income patients would exert its impact at the level of individual patients, and therefore be a patient-level effect.

It is also important to note that the patient-level and hospital-level coefficients cannot be quantitatively compared because the patient's SES circumstance in the model is binary whereas the hospital's proportion of low SES patients is continuous. Therefore, in order to quantitatively compare the relative size of the patient and hospital effects, we calculated a range of predicted probabilities of readmission based on the fitted model.

Specifically, to estimate an average hospital effect, we calculated the predicted probabilities for the following scenarios: (1) Assuming all patients do not have the risk factor (X_{ij} =0) and hospital level risk factor is at 5% percentile (P5) of all hospital values; (2) Assuming all patients do not have the risk factor and hospital level risk factor is at 95% percentile (P95); (3) Assuming all patients do have the risk factor (X_{ij} =1) and hospital level risk factor is at 5% percentile (P5); (4) Assuming all patients have the risk factor and hospital level risk factor is at 95% percentile (P5). The average hospital effect is estimated by ((2)-(1) + (4)-(3))/2 (P95-P5). Then, to estimate an average patient effect, we first calculated the predicted probabilities by assuming patient-level risk factor equal to 0 or 1 at different hospital risk factor percentiles (0%, 5%, 10%, 25%, 50%, 75%, 90%, 95%, and 100%). Then at each of those percentiles, we could obtain the difference of predicted probabilities between all patients not having the risk factor and then all patients having the risk factor. We calculated the average of those differences in predicted probabilities ('delta') as the patient effect.

In summary, the difference in predicted probabilities at the 95th and 5th percentiles (P95-P5) estimates the hospital-level effect of the SRF on readmission. The difference in predicted probabilities when all patients have and do not have the SES risk factor (delta) estimates the patient-level effect of the SES risk factor on readmission. The hospital-level effect is greater than the patient-level effect when P95-P5 is greater than delta. We used P95 and P5 rather than the maximum (P100) and minimum (P0) to avoid outlier values.

We also performed the same analysis for several clinical covariates to contrast the relative contributions of patient- and hospital-level effects of clinical variables to the relative contributions for the SRFs.

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2b3.3b. How was the conceptual model of how social risk impacts this outcome developed? Please check all that apply:

- $oxed{imed}$ Published literature
- \boxtimes Internal data analysis
- □ Other (please describe)

2b3.4a. What were the statistical results of the analyses used to select risk factors?

The table below shows the final variables in the model in the testing dataset with associated odds ratios (OR) and 95 percent confidence intervals (CI).

Table 4. Adjusted OR and 95% CIs for the COPD Hierarchical Logistic Regression Model over Different Time Periods in the **Testing Dataset**

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95%	OR (95%	OR (95%	OR (95%
	CI)	Cl)	Cl)	Cl)
Age minus 65 (years above 65, continuous)	1.00	1.00	1.00	1.00
	(1.00-	(1.00-	(0.99-	(1.00-
	1.00)	1.00)	1.00)	1.00)
History of mechanical ventilation	1.18	1.22	1.19	1.19
	(1.14-	(1.18-	(1.15-	(1.17-
	1.21)	1.25)	1.23)	1.21)
Sleep-disordered breathing	0.99	0.99	0.98	0.99
	(0.97-	(0.97-	(0.95-	(0.97-
	1.01)	1.01)	1.00)	1.00)
Severe infection; other infectious diseases (CC 1, 3-7)	1.07	1.05	1.07	1.06
	(1.05-	(1.03-	(1.04-	(1.05-
	1.09)	1.08)	1.09)	1.07)
Metastatic cancer and acute leukemia (CC 8)	1.26	1.17	1.18	1.21
	(1.19-	(1.10-	(1.12-	(1.17-
	1.32)	1.23)	1.26)	1.24)

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95%	OR (95%	OR (95%	OR (95%
	Cl)	Cl)	Cl)	Cl)
Lung and other severe cancers (CC 9)	1.17	1.22	1.19	1.19
	(1.13-	(1.17-	(1.14-	(1.17-
	1.21)	1.26)	1.23)	1.22)
Lymphatic, head and neck, brain, and other major cancers;	1.01	1.05	1.04	1.03
breast, colorectal and other cancers and tumors; other	(0.98-	(1.02-	(1.01-	(1.01-
respiratory and heart neoplasms (CC 10-13)	1.04)	1.08)	1.08)	1.05)
Other digestive and urinary neoplasms (CC 14)	0.94	0.95	0.94	0.94
	(0.91-	(0.91-	(0.91-	(0.92-
	0.98)	0.98)	0.98)	0.96)
Diabetes mellitus (DM) or DM complications (CC 17-19, 122- 123)	1.07 (1.05- 1.09)	1.07 (1.04- 1.09)	1.07 (1.05- 1.10)	1.07 (1.06- 1.08)
Protein-calorie malnutrition (CC 21)	1.14	1.12	1.16	1.14
	(1.11-	(1.09-	(1.13-	(1.12-
	1.17)	1.15)	1.20)	1.16)
Morbid obesity; other endocrine/metabolic/nutritional disorders (CC 22, 25-26)	0.94	0.94	0.95	0.94
	(0.92-	(0.91-	(0.92-	(0.93-
	0.97)	0.97)	0.98)	0.96)
Other significant endocrine and metabolic disorders; disorders of fluid/electrolyte/acid-base balance (CC 23-24)	1.17 (1.14- 1.19)	1.18 (1.16- 1.21)	1.17 (1.14- 1.20)	1.17 (1.16- 1.19)
Chronic pancreatitis (CC 34)	1.08	1.07	1.11	1.09
	(0.97-	(0.95-	(0.98-	(1.02-
	1.21)	1.21)	1.26)	1.17)
Peptic ulcer, hemorrhage, other specified gastrointestinal disorders (CC 36)	1.06	1.04	1.07	1.06
	(1.04-	(1.01-	(1.04-	(1.04-
	1.09)	1.07)	1.11)	1.08)
Other gastrointestinal disorders (CC 38)	1.05	1.08	1.07	1.06
	(1.03-	(1.05-	(1.04-	(1.05-
	1.07)	1.11)	1.10)	1.08)
Severe hematological disorders (CC 46)	1.15	1.20	1.17	1.17
	(1.06-	(1.10-	(1.06-	(1.11-
	1.24)	1.30)	1.29)	1.23)
Iron deficiency or other/unspecified anemias and blood disease (CC 49)	1.19	1.18	1.19	1.18
	(1.16-	(1.15-	(1.16-	(1.17-
	1.21)	1.20)	1.22)	1.20)
Dementia or other specified brain disorders (CC 51-53)	0.99	0.99	1.00	0.99
	(0.97-	(0.97-	(0.97-	(0.98-
	1.02)	1.02)	1.02)	1.01)

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95%	OR (95%	OR (95%	OR (95%
	CI)	Cl)	CI)	CI)
Drug/alcohol psychosis or dependence (CC 54-55)	1.20	1.19	1.16	1.19
	(1.16-	(1.15-	(1.12-	(1.16-
	1.24)	1.24)	1.21)	1.21)
Major psychiatric disorders (CC 57-59)	1.05	1.04	1.05	1.04
	(1.03-	(1.01-	(1.02-	(1.03-
	1.08)	1.07)	1.08)	1.06)
Depression (CC 61)	1.00	1.00	1.00	1.00
	(0.98-	(0.97-	(0.97-	(0.99-
	1.03)	1.02)	1.02)	1.01)
Anxiety disorders (CC 62)	1.07	1.06	1.05	1.06
	(1.04-	(1.03-	(1.01-	(1.04-
	1.10)	1.10)	1.08)	1.08)
Other psychiatric disorders (CC 63)	1.10	1.10	1.09	1.10
	(1.08-	(1.07-	(1.07-	(1.08-
	1.12)	1.12)	1.12)	1.11)
Hemiplegia, paraplegia, paralysis, functional disability (CC 70- 74, 103-104, 189-190)	1.08 (1.04- 1.12)	1.08 (1.03- 1.12)	1.07 (1.02- 1.11)	1.08 (1.05- 1.10)
Polyneuropathy; other neuropathies (CC 75, 81)	1.01	1.04	1.05	1.03
	(0.99-	(1.01-	(1.03-	(1.02-
	1.03)	1.06)	1.08)	1.05)
Respirator dependence/respiratory failure (CC 82-83)	0.98	1.01	1.02	1.00
	(0.91-	(0.94-	(0.95-	(0.96-
	1.04)	1.09)	1.11)	1.04)
Cardio-respiratory failure and shock (CC 84 plus ICD-10-CM codes R09.01 and R09.02, for discharges on or after October 1, 2015; CC 84 plus ICD-9-CM diagnosis codes 799.01 and 799.02, for discharges prior to October 1, 2015)	1.27	1.24	1.25	1.25
	(1.24-	(1.21-	(1.22-	(1.24-
	1.30)	1.27)	1.28)	1.27)
Congestive heart failure (CC 85)	1.23	1.22	1.22	1.22
	(1.20-	(1.19-	(1.19-	(1.20-
	1.26)	1.25)	1.25)	1.24)
Acute coronary syndrome (CC 86-87)	1.08	1.09	1.11	1.09
	(1.05-	(1.06-	(1.07-	(1.07-
	1.11)	1.13)	1.15)	1.11)
Coronary atherosclerosis or angina (CC 88-89)	1.10	1.07	1.06	1.08
	(1.07-	(1.05-	(1.04-	(1.06-
	1.12)	1.09)	1.09)	1.09)

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95%	OR (95%	OR (95%	OR (95%
	CI)	CI)	CI)	Cl)
Specified arrhythmias and other heart rhythm disorders (CC 96-97)	1.15	1.15	1.14	1.15
	(1.13-	(1.13-	(1.11-	(1.13-
	1.17)	1.18)	1.16)	1.16)
Other and unspecified heart disease (CC 98)	1.07	1.07	1.09	1.08
	(1.05-	(1.05-	(1.06-	(1.06-
	1.09)	1.10)	1.12)	1.09)
Stroke (CC 99-100)	1.00	1.00	1.09	1.03
	(0.97-	(0.96-	(1.05-	(1.00-
	1.04)	1.04)	1.14)	1.05)
Vascular or circulatory disease (CC 106-109)	1.07	1.05	1.06	1.06
	(1.05-	(1.03-	(1.03-	(1.05-
	1.09)	1.08)	1.08)	1.07)
Fibrosis of lung or other chronic lung disorders (CC 112)	1.08	1.09	1.11	1.09
	(1.05-	(1.06-	(1.08-	(1.07-
	1.11)	1.12)	1.14)	1.11)
COPD (CC 114-116)	1.05	1.06	1.06	1.06
	(1.03-	(1.04-	(1.04-	(1.04-
	1.07)	1.08)	1.09)	1.07)
Renal failure (CC 135-140)	1.15	1.15	1.15	1.15
	(1.13-	(1.12-	(1.12-	(1.13-
	1.17)	1.17)	1.17)	1.16)
Decubitus ulcer or chronic skin ulcer (CC 157-161)	1.10	1.08	1.08	1.09
	(1.07-	(1.04-	(1.04-	(1.07-
	1.14)	1.12)	1.12)	1.11)
Cellulitis, local skin infection (CC 164)	1.04	1.05	1.04	1.04
	(1.02-	(1.02-	(1.00-	(1.03-
	1.07)	1.08)	1.07)	1.06)
Vertebral fractures without spinal cord injury (CC 169)	1.12	1.14	1.14	1.13
	(1.08-	(1.09-	(1.09-	(1.10-
	1.16)	1.19)	1.19)	1.16)

2b3.4b. Describe the analyses and interpretation resulting in the decision to select social risk factors (*e.g. prevalence of the factor across measured entities, empirical association with the outcome, contribution of unique variation in the outcome, assessment of between-unit effects and within-unit effects.*) **Also describe the impact of adjusting for social risk (or not) on providers at high or low extremes of risk.**

Throughout this section, we present new SRF testing results based on the current testing dataset (2020); in addition, we show prior analyses included in the 2016 endorsement maintenance forms for comparison purposes.

Variation in prevalence of the factor across measured entities in 2020 and 2016 (Table 5)

SRFs	2020 Prevalence % (IQR)	2016 Prevalence % (IQR)
Dual	19.3% (11.5-28.8%)	20% (13.5-28.2%)
AHRQ Low SES	20.6% (7.60-37.5%)	14.6% (2.8-43.0%)

The prevalence of social risk factors in the COPD cohort varies widely across measured entities in 2020. The median percentage of dual-eligible patients was 19.3% (IQR 11.5%-28.8%) and the median percentage of patients with an AHRQSES index score adjusted for cost of living at the census block group level equal to or below 42.7 (lowest quartile) was 20.6% (IQR 7.60%-37.5%) in 2020. These results are consistent with the 2016 results presented above. The increase in dually-eligible patients may be due to a refinement in the definition that occurred since 2016.

Comparison of observed readmission rates in patients with and without social risk in 2020 and 2016 (Table 6)

SRFs	2020 Observed Rate	2016 Observed Rate
Dual (vs. Non-Dual)	22.7% (vs. 18.8%)	22.8% (vs. 19.6%)
AHRQ Low SES (vs. SES score above 42.7)	20.9% (vs 19.2%)	20.9% (vs. 20.0%)

The patient-level observed COPD readmission rates are higher for dual-eligible patients (22.7%) compared with 18.8% for non-dual patients in 2020. Similarly, the readmission rate for patients with an AHRQ SES index score equal to or below 42.7 was 20.9% compared with 19.2% for patients with an AHRQ SES index score above 42.7 in 2020. For both SRF variables, patient-level readmission rates have declined or remained stable among all characteristic groups of patients.

Incremental effect of SRF variables in a multivariable model in 2020 and 2016

We examined the strength and significance of the SRF variables in the context of a multivariable model. When we include these variables in a multivariable model that includes all of the claims-based clinical variables, the effect size of each of these variables is small. In 2020, dual-eligibility and the AHRQ SES index have effect sizes (odds ratios) of 1.07 and 1.06 when added independently to the model. Furthermore, the effect size of each variable is attenuated (1.06 and 1.05 for dual and SES) when both are added to the model.

We also find that the c-statistic is essentially unchanged with the addition of any of these variables into the model (Table 7).

COPD Readmission Models	2020 C-Statistic	2016 C-Statistic
Base Model: risk-adjusted model using the original clinical risk variables selected for the 2020 CMS public report of the pneumonia readmission measure	0.639	0.640
Base Model plus AHRQ Low SES based on beneficiary residential 9-digit ZIP codes (SES9) as a social risk variable	0.639	0.640
Base Model plus dual as a social risk variable	0.640	0.640
Base Model plus SES9 and dual as social risk variables	0.640	

Table 7.

Furthermore, we find that the addition of any of these variables into the model has little to no effect on hospital performance. We examined the change in hospitals' RSRRs with the addition of any of these variables. The median absolute change in hospitals' RSRRs when adding a dual-eligibility indicator is 0.014% (interquartile range [IQR] -0.012% -0.016%) with a correlation coefficient between RSRRs for each hospital with and without dual-eligibility added of 0.998. The median absolute change in hospitals' RSRRs when adding a low AHRQSES Index score indicator to the model is 0.101% (IQR -0.097% -0.104%) with a correlation coefficient between RSRRs for each hospital with and without an indicator for a low AHRQSES Index score adjusted for cost of living at the census block group level is 0.975.

Contextual Effect Analysis

As described in **2b3.3a**, we performed a decomposition analysis in **2020** and 2016 for each SRF variable to assess whether there was a corresponding contextual effect. In order to better interpret the magnitude of results, we performed the same analysis for selected clinical risk factors. The results are described in the tables/figures below.

Both the patient-level and hospital-level dual-eligibility, and low AHRQ SES Index effects were significantly associated with COPD readmission in the decomposition analysis. **That the hospital level effects were significant indicates that if the dual-eligible or low AHRQ SES Index variables were used in the model to adjust for patient-level differences, then some of the differences between hospitals would also be adjusted for, potentially obscuring a signal of hospital quality**.

To assess the relative contributions of the patient- and hospital-level effects, we calculated a range of predicted probabilities of readmission for the SRF variables and clinical covariates (comorbidities), as described in section **2b3.3a**. The results are presented in the figures and table below (table of predicted probabilities for SRF variables).

For the AHRQ SES index, the hospital-level effect (P95-P5) is greater than the patient-level effect (delta) (Figures 3 and 4; predicted probabilities for SRF variables); however, the patient-level effect is greater than the hospital-level effect for dual eligible status. For clinical variables, the patient-level effect (delta) is greater than the hospital-level effect (P95-P5) for severe cancer (Figures 3 and 4; predicted probabilities for clinical variables). The hospital-level effect (P95-P5) is greater than the patient-level effect (delta) for diabetes (Figures 3 and 4; predicted probabilities for clinical variables). In sum, including SRFs into the model would predominantly adjust for a hospital-level effect, which is an important signal of hospital quality.

In the context of our conceptual model, we find clear evidence supporting the first two mechanisms by which SRFs might be related to poor outcomes. First, we find that although unadjusted rates of readmission are higher for patients of low SES, the addition of SRFs to the readmission risk model, which already adjusts for clinical factors, makes very little difference. In particular, there is little-to-no change in model performance or hospital results with the addition of SRFs. This suggests that the model already largely accounts for the differences in clinical risk factors (degree of illness and comorbidities) among patients of varied SRFs.

Second, the predominance of the hospital-level effect of SRF variables in the decomposition analyses for 2020 and 2016 (Figures 3 and 4 below) suggests the risk associated with low SES is in large part due to lower quality of care at hospitals where more patients with these risk factors are treated; hospitals caring for socially- and economically-disadvantaged patients have higher readmission risk for all of their patients. Patients with low SES indicators tend to receive care more frequently at lower quality hospitals compared with patients with high SES indicators. Direct adjustment for patient SRFs would essentially "over adjust" the measure, that is to say, it would be adjusting for an endogenous factor, one that influences the outcome through the site of treatment (hospital), as much as through an attribute of the patient.

In comparison, we did not consistently observe the same predominance of the hospital-level effect among the clinical covariates, reinforcing the sense that SRFs have a distinct causal pathway in their impact on readmission risk.

Table 8. Parameter Estimates for Hospital-Level and Patient-Level in 2020 and 2016 from Decomposition Analysis

Parameter	2020 Estimate (standard error), p-value	2016 Estimate (standard error), p-value
Dual-Eligible – Patient Level	0.058 (0.007), <0.0001	0.084 (0.007), <0.0001
Dual-Eligible – Hospital Level	0.142 (0.026), <0.0001	0.208 (0.026), <0.0001
Low SES census block group (AHRQ SES index linked to 9-digit ZIP – Adjusted for Cost of Living) – Patient Level	0.473 (0.007), <0.0001	0.023 (0.008), <0.01
Low SES census block group (AHRQ SES index linked to 9-digit ZIP – Adjusted for Cost of Living) – Hospital Level	0.142 (0.022), <0.0001	0.077 (0.010), <0.0001

Figure 3. Decomposition Analysis for 2020, COPD Readmission

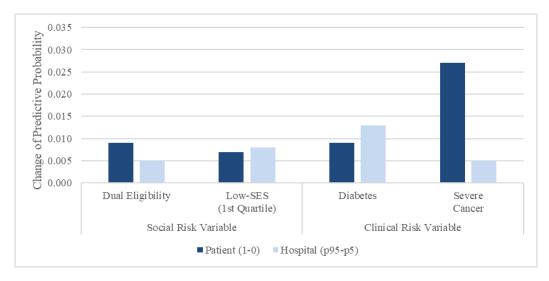
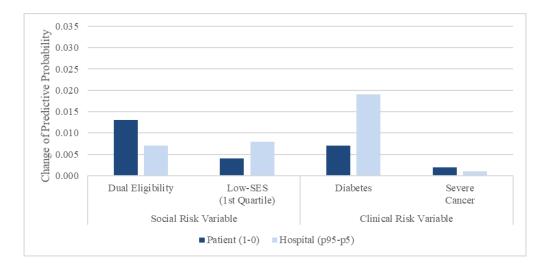


Figure 4. Decomposition Analysis for 2016, COPD Readmission



Summary

For risk-adjusted outcome measures, CMS first considers adjustment for clinical comorbidities, frailty indicators, and then examines additional risk imparted by SRFs after the potential for greater disease burden is included in the risk model (see section 2b3.3a). We believe that this is consistent with NQF current guidance and is appropriate given the evidence cited in our submission that people who experience greater social risk are more likely to have more disease burden compared with those who have less social risk; and that this is clearly not a signal of hospital quality. In addition, according to NQF guidance, developers should assess social risk factors for their contribution of unique variation in the outcome – that they are not redundant (NQF, 2014). Therefore, if clinical risk factors explain all or most of the patient variation in the outcome, then NQF guidance does not support adding social risk factors that do not account for variation. CMS's decisions about which risk factors should be included in each measure's risk-adjustment model are based on whether inclusion of such variables is likely to make the measures more successful at illuminating quality differences and motivating quality improvement. (This aim should be distinguished from decisions made in response to concerns about the impact of related payment programs on safety-net hospitals; concerns which can be addressed through other policy mechanisms.)

We found wide variation in the prevalence of the two SRFs we examined, with a large proportion of hospitals treating zero patients with these SRFs. We also found that both had some association with readmission risk. However, adjustment for these factors did not have a material impact on hospital RSRRs, suggesting that existing clinical risk factors capture much of the risk related to social risk. Therefore, we did not include these two SRFs in our final risk model.

Ongoing research aims to identify valid patient-level social risk factors and highlight disparities related to social risk – in fact, ASPE's latest report to Congress highlights which SRFs are valid in claims data, and that adjustment for SRFs in publicly reported quality measures is not recommended because providers should be accountable for overall outcomes, regardless of social risk (ASPE 2020). As additional variables become available, they will be considered for testing and inclusion within the measure. There are alternative ways to adjust for social risk as part of measure program implementation, such as stratification or peer grouping, which CMS recently applied to the Hospital Readmission Reduction Program (HRRP). CMS also confidentially reports disparities in the readmission measures to hospitals so that they have more detailed, actionable information about their patient population's social risk. Given these empiric findings and program considerations, CMS chose not to include these two SRFs in the final risk model at this time.

We acknowledge the importance of balancing these competing considerations and are committed to constant refinement and improvement of risk adjustment models used in all measures. We will continue to reevaluate this model and available risk factors on an ongoing basis, with the goal of producing the most accurate and fair risk adjustment models for assessing provider performance.

References:

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

National Quality Forum (NQF). Risk adjustment for socioeconomic status or other sociodemographic factors: Technical report. 2014;

http://www.qualityforum.org/Publications/2014/08/Risk Adjustment for Socioeconomic Status or Other S ociodemographic Factors.aspx. Accessed June 16, 2020.

2b3.5. Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach (describe the steps—do not just name a method; what statistical analysis was used)

Provide the statistical results from testing the approach to controlling for differences in patient characteristics (case mix) below.

If stratified, skip to <u>2b3.9</u>

Approach to assessing model performance

We computed three summary statistics for assessing model performance (Harrell and Shih, 2001) for the expanded cohort:

Discrimination Statistics

- 1. Area under the receiver operating characteristic (ROC) curve (the c-statistic) is the probability that predicting the outcome is better than chance, which is a measure of how accurately a statistical model is able to distinguish between a patient with and without an outcome)
- 2. Predictive ability (discrimination in predictive ability measures the ability to distinguish high-risk subjects from low-risk subjects; therefore, we would hope to see a wide range between the lowest decile and highest decile

Calibration Statistics

3. Over-fitting indices (over-fitting refers to the phenomenon in which a model accurately describes the relationship between predictive variables and outcome in the development dataset but fails to provide valid predictions in new patients)

We tested the performance of the model for **the development dataset** described in section 1.7.

References:

Harrell FE and Shih YC, Using full probability models to compute probabilities of actual interest to decision makers, *Int. J. Technol. Assess. Health Care* 17 (2001), pp. 17–26.

2b3.6. Statistical Risk Model Discrimination Statistics (e.g., c-statistic, R-squared):

For the development cohort the results are summarized below:

C-statistic = 0.627

Dataset Predictive ability (lowest decile %, highest decile %) = (11.57, 38.08)

For the validation cohort the results are summarized below:

C-statistic = 0.629

Dataset Predictive ability (lowest decile %, highest decile %) = (11.73, 39.19)

Results for the Testing Dataset

C-statistic = 0.64

Predictive ability (lowest decile %, highest decile %): (9.5, 35.8)

2b3.7. Statistical Risk Model Calibration Statistics (*e.g., Hosmer-Lemeshow statistic*):

For the original measure development cohort, the results are summarized below:

Development sample: Calibration: (-0.034, 0.970)

Validation sample: Calibration: (0.004, 0.994)

2b3.8. Statistical Risk Model Calibration – Risk decile plots or calibration curves:

The risk decile plot is a graphical depiction of the deciles calculated to measure predictive ability. Below, we present the risk decile plot showing the distributions for Medicare FFS data from July 2016 – June 2019 (Testing Dataset).

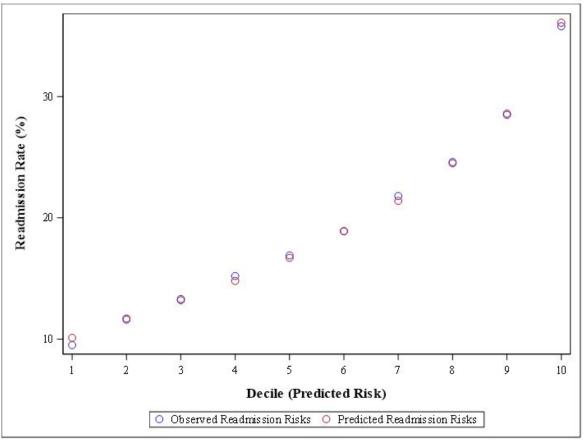


Figure 5. Risk Decile Plot

2b3.9. Results of Risk Stratification Analysis:

N/A

2b3.10. What is your interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix)? (i.e., what do the results mean and what are the norms for the test conducted)

Discrimination Statistics

The c-statistic of 0.64 indicate fair model discrimination. The model indicated a wide range between the lowest decile and highest decile, indicating the ability to distinguish high-risk subjects from low-risk subjects.

Calibration Statistics

Over-fitting (Calibration γ0, γ1)

If the $\gamma 0$ in the validation samples are substantially far from zero and the $\gamma 1$ is substantially far from one, there is potential evidence of over-fitting. The calibration value of close to 0 at one end and close to 1 to the other end indicates calibration of the model.

Risk Decile Plots

Higher deciles of the predicted outcomes are associated with higher observed outcomes, which show a good calibration of the model. This plot indicates good discrimination of the model and good predictive ability.

Overall Interpretation

Interpreted together, our diagnostic results demonstrate the risk-adjustment model adequately controls for differences in patient characteristics (case mix) and is comparable to other (add outcome name [e.g. readmission, mortality, etc.]) outcome measures.

2b3.11. Optional Additional Testing for Risk Adjustment (*not required*, but would provide additional support of adequacy of risk model, e.g., testing of risk model in another data set; sensitivity analysis for missing data; other methods that were assessed)

N/A

2b4. IDENTIFICATION OF STATISTICALLY SIGNIFICANT & MEANINGFUL DIFFERENCES IN PERFORMANCE

2b4.1. Describe the method for determining if statistically significant and clinically/practically meaningful differences in performance measure scores among the measured entities can be identified (describe the steps—do not just name a method; what statistical analysis was used? Do not just repeat the information provided related to performance gap in 1b)

The measure score is hospital-specific risk-standardized readmission rates (RSRRs). These rates are obtained as the ratio of predicted to expected readmissions, multiplied by the national unadjusted rate. The "predicted" number of readmissions (the numerator) is calculated using the coefficients estimated by regressing the risk factors and the hospital-specific intercept on the risk of readmissions. The estimated hospital-specific intercept is added to the sum of the estimated regression coefficients multiplied by the patient characteristics. The results are then transformed and summed over all patients attributed to a hospital to get a predicted value. The "expected" number of readmissions (the denominator) is obtained in the same manner, but a common intercept using all hospitals in our sample is added in place of the hospital-specific intercept. The results are then transformed and summed over all patients in the hospital to get an expected value. To assess hospital performance for each reporting period, we re-estimated the model coefficients using the years of data in that period.

We characterize the degree of variability by:

1) Reporting the distribution of RSRRs:

For public reporting of the measure, CMS characterizes the uncertainty associated with the RSRR by estimating the 95% interval estimate. This is similar to a 95% confidence interval but is calculated differently. If the RSRR's interval estimate does not include the national observed readmission rate (because it is lower or higher than the rate), then CMS is confident that the hospital's RSRR is different from the national rate, and describes the hospital on the *Hospital Compare* website as "better than the U.S. national rate" or "worse than the U.S. national rate." If the interval includes the national rate, then CMS describes the hospital's RSRR as "no different than the U.S. national rate" or "the difference is uncertain." CMS does not classify performance for hospitals that have fewer than 25 cases in the three-year period.

2) Providing the median odds ratio (MOR) (Merlo et al, 2006). The median odds ratio represents the median increase in the odds of a readmission within 30 days of a COPD admission date on a single

patient if the admission occurred at a higher risk hospital compared to a lower risk hospital. MOR quantifies the between hospital variance in terms of odds ratio, it is comparable to the fixed effects odds ratio.

Reference:

Merlo J, Chaix B, Ohlsson H, Beckman A, Johnell K, Hjerpe P, Råstam L, Larsen K. (2006) A brief conceptual tutorial of multilevel analysis in social epidemiology: Using measures of clustering in multilevel logistic regression to investigate contextual phenomena. J Epidemiol Community Health, 60(4):290-7.

2b4.2. What were the statistical results from testing the ability to identify statistically significant and/or clinically/practically meaningful differences in performance measure scores across measured entities? (e.g., number and percentage of entities with scores that were statistically significantly different from mean or some benchmark, different from expected; how was meaningful difference defined)

Analyses of Medicare FFS data show substantial variation in RSRRs among hospitals.

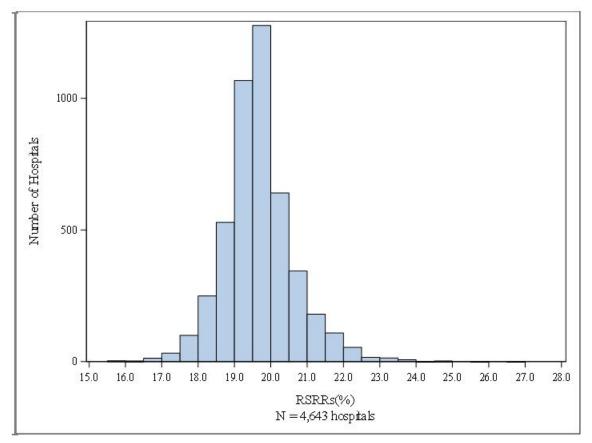


Figure 6. Distribution (Histogram) Of Hospital-Level COPD RSRRs

Out of 4,643 hospitals in the measure cohort, 14 performed "better than the U.S. national rate," 3,680 performed "no different from the U.S. national rate," and 52 performed "worse than the U.S. national rate." 897 were classified as "number of cases too small" (fewer than 25) to reliably tell how well the hospital is performing.

The median odds ratio was 1.13.

2b4.3. What is your interpretation of the results in terms of demonstrating the ability to identify statistically significant and/or clinically/practically meaningful differences in performance across measured entities? (i.e., what do the results mean in terms of statistical and meaningful differences?)

The median odds ratio suggests a meaningful increase in the risk of readmission if a patient is admitted with COPD at a higher risk hospital compared to a lower risk hospital. A value of 1.13 indicates that a patient's risk of readmission is 13% times greater in a higher risk hospital than a lower risk hospital.

2b5. COMPARABILITY OF PERFORMANCE SCORES WHEN MORE THAN ONE SET OF SPECIFICATIONS

If only one set of specifications, this section can be skipped.

Note: This item is directed to measures that are risk-adjusted (with or without social risk factors) **OR** to measures with more than one set of specifications/instructions (e.g., one set of specifications for how to identify and compute the measure from medical record abstraction and a different set of specifications for claims or eMeasures). It does not apply to measures that use more than one source of data in one set of specification for the numerator). Comparability is not required when comparing performance scores with and without social risk factors in the risk adjustment model. However, if comparability is not demonstrated for measures with more than one set of specifications/instructions, the different specifications (e.g., for medical records vs. claims) should be submitted as separate measures.

2b5.1. Describe the method of testing conducted to compare performance scores for the same entities across the different data sources/specifications (*describe the steps—do not just name a method; what statistical analysis was used*)

N/A

2b5.2. What were the statistical results from testing comparability of performance scores for the same entities when using different data sources/specifications? (*e.g., correlation, rank order*)

N/A

2b5.3. What is your interpretation of the results in terms of the differences in performance measure scores for the same entities across the different data sources/specifications? (i.e., what do the results mean and what are the norms for the test conducted)

N/A

2b6. MISSING DATA ANALYSIS AND MINIMIZING BIAS

2b6.1. Describe the method of testing conducted to identify the extent and distribution of missing data (or nonresponse) and demonstrate that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias (*describe the steps—do not just name a method; what statistical analysis was used*)

The COPD readmission measure used claims-based data for development and testing. There was no missing data in the development and testing data.

2b6.2. What is the overall frequency of missing data, the distribution of missing data across providers, and the results from testing related to missing data? (*e.g.*, results of sensitivity analysis of the effect of various rules for missing data/nonresponse; if no empirical sensitivity analysis, identify the approaches for handling missing data that were considered and pros and cons of each)

N/A

2b6.3. What is your interpretation of the results in terms of demonstrating that performance results are not biased due to systematic missing data (or differences between responders and non-responders) and how the specified handling of missing data minimizes bias? (i.e., what do the results mean in terms of supporting the selected approach for missing data and what are the norms for the test conducted; if no empirical analysis, provide rationale for the selected approach for missing data)

N/A

3. Feasibility

Extent to which the specifications including measure logic, require data that are readily available or could be captured without undue burden and can be implemented for performance measurement.

3a. Byproduct of Care Processes

For clinical measures, the required data elements are routinely generated and used during care delivery (e.g., blood pressure, lab test, diagnosis, medication order).

3a.1. Data Elements Generated as Byproduct of Care Processes.

Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims) If other:

3b. Electronic Sources

The required data elements are available in electronic health records or other electronic sources. If the required data are not in electronic health records or existing electronic sources, a credible, near-term path to electronic collection is specified.

3b.1. To what extent are the specified data elements available electronically in defined fields (*i.e.*, data elements that are needed to compute the performance measure score are in defined, computer-readable fields) Update this field for *maintenance of endorsement*.

ALL data elements are in defined fields in electronic claims

3b.2. If ALL the data elements needed to compute the performance measure score are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources. For *maintenance of endorsement*, if this measure is not an eMeasure (eCQM), please describe any efforts to develop an eMeasure (eCQM).

N/A

3b.3. If this is an eMeasure, provide a summary of the feasibility assessment in an attached file or make available at a measure-specific URL. Please also complete and attach the NQF Feasibility Score Card.

Attachment:

3c. Data Collection Strategy

Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, costs associated with fees/licensing of proprietary measures) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use). For eMeasures, a feasibility assessment addresses the data elements and measure logic and demonstrates the eMeasure can be implemented or feasibility concerns can be adequately addressed.

3c.1. *Required for maintenance of endorsement.* Describe difficulties (as a result of testing and/or operational use of the measure) regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues.

IF instrument-based, consider implications for both individuals providing data (patients, service recipients, respondents) and those whose performance is being measured.

This measure uses administrative claims and enrollment data and as such, offers no data collection burden to hospitals or providers.

3c.2. Describe any fees, licensing, or other requirements to use any aspect of the measure as specified (*e.g.*, value/code set, risk model, programming code, algorithm).

4. Usability and Use

Extent to which potential audiences (e.g., consumers, purchasers, providers, policy makers) are using or could use performance results for both accountability and performance improvement to achieve the goal of highquality, efficient healthcare for individuals or populations.

4a. Accountability and Transparency

Performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement (or the data on performance results are available). If not in use at the time of initial endorsement, then a credible plan for implementation within the specified timeframes is provided.

4.1. Current and Planned Use

NQF-endorsed measures are expected to be used in at least one accountability application within 3 years and publicly reported within 6 years of initial endorsement in addition to performance improvement.

Specific Plan for Use	Current Use (for current use provide URL)
Not in use	Public Reporting
	Hospital Compare
	https://www.medicare.gov/hospitalcompare/search.html?
	Hospital Compare
	https://www.medicare.gov/hospitalcompare/search.html?
	Payment Program
	Hospital Readmission Reduction (HRRP) Program
	https://www.qualitynet.org/inpatient/hrrp
	Hospital Readmission Reduction (HRRP) Program
	https://www.qualitynet.org/inpatient/hrrp

4a1.1 For each CURRENT use, checked above (update for *maintenance of endorsement*), provide:

- Name of program and sponsor
- Purpose
- Geographic area and number and percentage of accountable entities and patients included
- Level of measurement and setting

Public Reporting

Program Name, Sponsor: Hospital Compare, Centers for Medicare and Medicaid Services (CMS) Purpose: Under Hospital Compare and other CMS public reporting websites, CMS collects quality data from hospitals, with the goal of driving quality improvement through measurement and transparency by publicly displaying data to help consumers make more informed decisions about their health care. It is also intended to encourage hospitals and clinicians to improve the quality and cost of inpatient care provided to all patients. The data collected are available to consumers and providers on the Hospital Compare website at: https://www.medicare.gov/hospitalcompare/search.html. Data for selected measures are also used for paying a portion of hospitals based on the quality and efficiency of care, including the Hospital Value-Based Purchasing Program, Hospital-Acquired Condition Reduction Program, and Hospital Readmissions Reduction Program.

Payment Program

Program Name, Sponsor: Hospital Readmission Reduction Program (HRRP), Centers for Medicare and Medicaid Services (CMS)

Purpose: Section 3025 of the Affordable Care Act added section 1886(q) to the Social Security Act establishing the Hospital Readmissions Reduction Program, which requires CMS to reduce payments to IPPS hospitals with excess readmissions, effective for discharges beginning on October 1, 2012. The regulations that implement this provision are in subpart I of 42 CFR part 412 (§412.150 through §412.154).

Geographic area and number and percentage of accountable entities and patients included: The HRRP program includes only Subsection (d) hospitals and hospitals located in Maryland. Subsection (d) hospital encompasses any acute care hospital located in one of the fifty states or the District of Columbia which does not meet any of the following exclusion criteria as defined by the Social Security Act: psychiatric, rehabilitation, children's, or long-term care hospitals, and non-IPPS cancer hospitals. Critical access hospitals, non-IPPS cancer hospitals, and hospitals located in U.S territories are not included in the calculation. The number and percentage of accountable entities included in the program, as well as the number of patients included in the measure, varies by reporting year.

4a1.2. If not currently publicly reported OR used in at least one other accountability application (e.g., payment program, certification, licensing) what are the reasons? (e.g., Do policies or actions of the developer/steward or accountable entities restrict access to performance results or impede implementation?) N/A. This measure is currently publicly reported.

4a1.3. If not currently publicly reported OR used in at least one other accountability application, provide a credible plan for implementation within the expected timeframes -- any accountability application within 3 years and publicly reported within 6 years of initial endorsement. (*Credible plan includes the specific program, purpose, intended audience, and timeline for implementing the measure within the specified timeframes. A plan for accountability applications addresses mechanisms for data aggregation and reporting.*)

N/A. This measure is currently publicly reported.

4a2.1.1. Describe how performance results, data, and assistance with interpretation have been provided to those being measured or other users during development or implementation.

How many and which types of measured entities and/or others were included? If only a sample of measured entities were included, describe the full population and how the sample was selected.

The exact number of measured entities (acute care hospitals) varies with each new measurement period. For the period between 2016 – 2019, all non-federal short-term acute care hospitals (including Indian Health Service hospitals), critical access hospitals, and VA hospitals (4,643 hospitals) were included in the measure calculation. Only those hospitals with at least 25 COPD admissions were included in public reporting.

Each hospital receives their measure results in April/May of each calendar year through CMS's QualityNet website. The results are then publicly reported on CMS's Hospital Compare website in July of each calendar year. Since the measure is risk standardized using data from all hospitals, hospitals cannot independently calculate their score.

However, CMS provides each hospital with several resources that aid in the interpretation of their results (described in detail below). These include Hospital-Specific Reports with details about every patient from their facility that was included in the measure calculation (for example, dates of admission and discharge, discharge diagnoses, outcome [died or not], transfer status, and facility transferred from). These reports facilitate quality improvement activities such as review of individual deaths and patterns of deaths; make visible to hospitals post-discharge outcomes that they may otherwise be unaware of; and allow hospitals to look for patterns that may inform quality improvement (QI) work (e.g. among patient transferred in from particular facilities). CMS also provides measure FAQs, webinars, and measure-specific question and answer inboxes for stakeholders to ask specific questions.

The Hospital-Specific Reports also provide hospitals with more detailed benchmarks with which to gauge their performance relative to peer hospitals and interpret their results, including comorbidity frequencies for their patients relative to other hospitals in their state and the country.

Additionally, the code used to process the claims data and calculate measure results is written in SAS (Cary, NC) and is provided each year to hospitals upon request.

4a2.1.2. Describe the process(es) involved, including when/how often results were provided, what data were provided, what educational/explanatory efforts were made, etc.

During the Spring of each year, hospitals have access to the following list of updated resources related to the measure which is provided directly or posted publicly for hospitals to use:

- 1. Hospital-Specific Reports (HSR): available for hospitals to download from QualityNet in April/May of each calendar year; includes information on the index admissions included in the measure calculation for each facility, detailed measure results, and state and national results.
- 2. HSR User Guide: available with the HSR and posted on QualityNet; provides instructions for interpreting the results and descriptions of each data field in the HSR.
- 3. Mock HSR: posted on QualityNet; provides real national results and simulated state and hospital results for stakeholders who do not receive an HSR.
- 4. HSR Tutorial Video: A brief animated video to help hospitals navigate their HSR and interpret the information provided.
- 5. Public Reporting Preview and Preview Help Guide: available for hospitals to view from QualityNet in Spring of each calendar year; includes measure results that will be publicly reported on CMS's public reporting websites.
- 6. Annual Updates and Specification Reports: posted in April/May of each calendar year on QualityNet with detailed measure specifications, descriptions of changes made to the measure specifications with rationale and impact analysis (when appropriate), updated risk variable frequencies and coefficients for the national cohort, and updated national results for the new measurement period.
- 7. Frequently asked Questions (FAQs): includes general and measure-specific questions and responses, as well as infographics that explain complex components of the measure's methodology, and are posted in April/May of each calendar year on QualityNet.
- 8. The SAS code used to calculate the measure with documentation describing what data files are used and how the SAS code works. This code and documentation are updated each year and are released upon request beginning in July of each year.
- 9. Measure Fact Sheets: provides a brief overview of measures, measure updates, and are posted in April/May of each calendar year on QualityNet.

During the summer of each year, the publicly-reported measure results are posted on CMS's public reporting websites, a tool to find hospitals and compare their quality of care that CMS created in collaboration with organizations representing consumers, hospitals, doctors, employers, accrediting organizations, and other federal agencies. Measure results are updated in July of each calendar year.

4a2.2.1. Summarize the feedback on measure performance and implementation from the measured entities and others described in 4d.1.

Describe how feedback was obtained.

Question and Answer Inbox (Q&A)

The measured entities (acute care hospitals) and other stakeholders or interested parties submit questions or comments about the measure through an email inbox (CMSreadmissionmeasures@yale.edu). Experts on measure specifications, calculation, or implementation, prepare responses to those inquiries and reply directly to the sender. We consider issues raised through the Q&A process about measure specifications or measure calculation in measure reevaluation.

Literature Reviews

In addition, we routinely scan the literature for scholarly articles describing research related to this measure. We summarize new information obtained through these reviews every 3 years as a part of comprehensive reevaluation as mandated by the Measure Management System (MMS) Blueprint.

4a2.2.2. Summarize the feedback obtained from those being measured.

Summary of Questions or Comments from Hospitals submitted through the Q & A process:

For the COPD readmission measure, we have received the following inquiries from hospitals since the last endorsement maintenance cycle:

- 1. Requests for detailed measure specifications including the ICD-9 and ICD-10 codes used to define the measure cohort or in the risk-adjustment model;
- 2. Requests for the SAS code used to calculate measure results;
- 3. Requests about the data source used to calculate the measure;
- 4. Questions about how transfers are handled in the measure calculation;
- 5. Requests for hospital-specific measure information such as HSRs; and
- 6. Requests for clarification of how inclusion and exclusion criteria are applied;
- 7. Question on national COPD readmission rates;
- 8. Question on how multiple readmissions within 30-days of an index admission are counted;
- 9. Queries about how cohorts and outcomes are defined including whether there is overlap in the cohorts and outcomes assessed in the COPD and heart failure readmission measures; and
- 10. Queries about the statistical methods of the measure including, the metric required to meet the standard to fall into the "better than national rate."

4a2.2.3. Summarize the feedback obtained from other users

Summary of Question and Comments from Other Stakeholders:

For the COPD readmission measure, we have received the following feedback from other stakeholders since the last endorsement maintenance cycle:

- 1. Requests for detailed measure specifications including the narrative specifications for the measure, CC-to-ICD-9 code crosswalks, and ICD-9 and ICD-10 codes used to define the measure cohort or in the riskadjustment model;
- 2. Requests for the data source and the SAS code used to calculate measure results;
- 3. Requests for clarification of how inclusion and exclusion criteria are applied;
- 4. Queries about how cohorts and outcomes are defined, including how planned readmissions are defined;
- 5. Request for COPD RSRR for VA hospitals; and
- 6. Request for state-level COPD readmission rate data.

Summary of Relevant Publications from the Literature Review:

Since the last endorsement cycle, we have reviewed 170 articles related to readmission following COPD admissions. Relevant articles shared key themes related to: differential care patterns across varying hospital types and provider types; considerations for additional risk adjustment variables, including social risk factors and other clinical comorbidities; association between hospital COPD admission volume and outcomes; and, effectiveness of transitional care models and community intervention initiatives on reducing readmissions.

4a2.3. Describe how the feedback described in 4a2.2.1 has been considered when developing or revising the measure specifications or implementation, including whether the measure was modified and why or why not.

Each year, issues raised through the Q&A or in the literature related to this measure are considered by measure and clinical experts. Any issues that warrant additional analytic work due to potential changes in the measure specifications are addressed as a part of annual measure reevaluation. If small changes are indicated after additional analytic work is complete, those changes are usually incorporated into the measure in the next measurement period. If the changes are substantial, CMS may propose the changes through rulemaking and adopt the changes only after CMS received public comment on the changes and finalizes those changes in the IPPS or other rule. There were no questions or issues raised by stakeholders requiring additional analysis or changes to the measure since the last endorsement maintenance cycle.

Improvement

Progress toward achieving the goal of high-quality, efficient healthcare for individuals or populations is demonstrated. If not in use for performance improvement at the time of initial endorsement, then a credible rationale describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

4b1. Refer to data provided in 1b but do not repeat here. Discuss any progress on improvement (trends in performance results, number and percentage of people receiving high-quality healthcare; Geographic area and number and percentage of accountable entities and patients included.)

If no improvement was demonstrated, what are the reasons? If not in use for performance improvement at the time of initial endorsement, provide a credible rationale that describes how the performance results could be used to further the goal of high-quality, efficient healthcare for individuals or populations.

The median hospital 30-day, all-cause, RSRR for the COPD readmission measure for the 3-year period between July 1, 2016 and June 30, 2019 was 19.6%. The median RSRR increased by 0.1 absolute percentage points from July 2016-June 2017 (median RSRR: 19.5%) to July 2018-June 2019 (median: RSRR: 19.6%).

We expected an increase in the observed COPD readmission rate between 2017-2018 due to a worse than normal flu season, though flu severity was moderate from 2018-2019 (CDC). Overall, COPD mortality rates appear to be fairly stable after years of decline.

4b2. Unintended Consequences

The benefits of the performance measure in facilitating progress toward achieving high-quality, efficient healthcare for individuals or populations outweigh evidence of unintended negative consequences to individuals or populations (if such evidence exists).

4b2.1. Please explain any unexpected findings (positive or negative) during implementation of this measure including unintended impacts on patients.

N/A

4b2.2. Please explain any unexpected benefits from implementation of this measure.

N/A

5. Comparison to Related or Competing Measures

If a measure meets the above criteria **and** there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure.

5. Relation to Other NQF-endorsed Measures

Are there related measures (conceptually, either same measure focus or target population) or competing measures (conceptually both the same measure focus and same target population)? If yes, list the NQF # and title of all related and/or competing measures.

Yes

5.1a. List of related or competing measures (selected from NQF-endorsed measures)

0275 : Chronic Obstructive Pulmonary Disease (COPD) or Asthma in Older Adults Admission Rate (PQI 05) 0506 : Hospital 30-day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Pneumonia Hospitalization

1789 : Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)

1893 : Hospital 30-Day, all-cause, risk-standardized mortality rate (RSMR) following chronic obstructive pulmonary disease (COPD) hospitalization

2879 : Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and Electronic Health Record Data

2888 : Accountable Care Organization Risk-Standardized Acute Hospital Admission Rate for Patients with Multiple Chronic Conditions

5.1b. If related or competing measures are not NQF endorsed please indicate measure title and steward.

5a. Harmonization of Related Measures

The measure specifications are harmonized with related measures;

OR

The differences in specifications are justified

5a.1. If this measure conceptually addresses EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):

Are the measure specifications harmonized to the extent possible?

Yes

5a.2. If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden.

We did not include in our list of related measures any non-outcome (e.g., process) measures with the same target population as our measure. Because this is an outcome measure, clinical coherence of the cohort takes precedence over alignment with related non-outcome measures. Furthermore, non-outcome measures are limited due to broader patient exclusions. This is because they typically only include a specific subset of patients who are eligible for that measure (for example, patients who receive a specific medication or undergo a specific procedure).

5b. Competing Measures

The measure is superior to competing measures (e.g., is a more valid or efficient way to measure); **OR**

Multiple measures are justified.

5b.1. If this measure conceptually addresses both the same measure focus and the same target population as NQF-endorsed measure(s):

Describe why this measure is superior to competing measures (e.g., a more valid or efficient way to measure quality); OR provide a rationale for the additive value of endorsing an additional measure. (Provide analyses when possible.)

N/A

Appendix

A.1 Supplemental materials may be provided in an appendix. All supplemental materials (such as data collection instrument or methodology reports) should be organized in one file with a table of contents or bookmarks. If material pertains to a specific submission form number, that should be indicated. Requested information should be provided in the submission form and required attachments. There is no guarantee that supplemental materials will be reviewed.

Available at measure-specific web page URL identified in S.1 Attachment:

Contact Information

Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services

Co.2 Point of Contact: Helen, Dollar-Maples, Helen. Dollar-Maples@cms. hhs.gov, 410-786-7214-

Co.3 Measure Developer if different from Measure Steward: Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE)

Co.4 Point of Contact: Doris, Peter, yalecoreNQF@yale.edu

Additional Information

Ad.1 Workgroup/Expert Panel involved in measure development

Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.

The working group involved in the initial measure development is detailed in the original technical report available at www.qualitynet.org.

Our measure development team consisted of the following members:

Laura M. Grosso, PhD, MPH

Peter Lindenauer, MD, MSc

Changqin Wang, MD, MS

Shantal Savage, BA

Jaymie Potteiger, MPH

Zameer Abedin, BA

Lori L. Geary, MPH

Yun Wang, PhD

Elizabeth E. Drye, MD, SM

Harlan M. Krumholz, MD, SM

Technical Expert Panel Members:

Darlene Bainbridge, MS, NHA, CPHQ, CPHRM, President/CEO, Darlene D. Bainbridge & Associates, Inc.

Robert A. Balk, MD, Director of Pulmonary and Critical Care Medicine, Rush University Medical Center

Dale Bratzler, DO, MPH, President and CEO, Oklahoma Foundation for Medical Quality

Scott Cerreta, RRT, Director of Education, COPD Foundation

Gerard J. Criner, MD, Director of Temple Lung Center and Divisions of Pulmonary and Critical Care Medicine, Temple University

Guy D' Andrea, MBA, Discern Consulting

Jonathan Fine, MD, Director of Pulmonary Fellowship, Research and Medical Education, Norwalk Hospital

David Hopkins, MS, PHD, Senior Advisor, Pacific Business Group on Health

Fred Martin Jacobs, MD, JD, FACP, FCCP, FCLM, Executive Vice President and Director, Saint Barnabas Quality Institute

Natalie Napolitano, MPH, RRT-NPS, Respiratory Therapist, Inova Fairfax Hospital

Russell Robbins, MD, MBA, Principal and Senior Clinical Consultant, Mercer

Working Group Panel Members:

David Au, MD, MS, Investigator, VA Puget Sound Healthcare System, Northwest HSR&D Center of Excellence; Associate Professor of Medicine, Department of Medicine, University of Washington Jerry Krishnan, MD, PhD, Associate Professor, Departments of Medicine and Health Studies, University of Chicago;

Director, Asthma Center and Refractory Obstructive Lung Disorders Clinic, University of Chicago

Todd Lee, PharmD, PhD, Associate Professor, Departments of Pharmacy Practice and Pharmacy Administration, University of Illinois at Chicago; Senior Investigator, Center for Management of Complex Chronic Care (CMC3), Hines VA Hospital

Richard Mularski, MD, MCR, MSHS, Clinical Investigator, Center for Health Research, Kaiser Permanente; Clinical Assistant Professor of Medicine, Oregon Health & Science University

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2014

Ad.3 Month and Year of most recent revision: 12, 2019

Ad.4 What is your frequency for review/update of this measure? Annual

Ad.5 When is the next scheduled review/update for this measure? 2020

Ad.6 Copyright statement: N/A

Ad.7 Disclaimers: N/A

Ad.8 Additional Information/Comments: N/A