

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 #: 2515

Corresponding Measures:

De.2. Measure Title: Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery

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

De.3. Brief Description of Measure: The measure estimates a hospital-level risk-standardized readmission rate (RSRR), defined as unplanned readmission for any cause within 30-days from the date of discharge for a qualifying index CABG procedure, in patients 65 years and older.

An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the readmission outcome.

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 CABG surgery are influenced by complex and critical aspects of care, such as: communication between providers; prevention of, and response to, complications; patient safety; 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 measure was developed to identify institutions whose performance is better or worse than would be expected based on each institution's 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 a qualifying isolated CABG procedure, CABG readmissions are a priority area for outcome measure development. 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 readmissions. We define readmission as an inpatient acute care admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index admission for an isolated CABG surgery in patients 65 and

older. 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 who are age 65 and older with a qualifying isolated CABG procedure and complete claims history for the 12 months prior to the index admission.

S.8. Denominator Exclusions: For all cohorts, hospitalizations are excluded if they meet any of the following criteria, for admissions:

- 1. Without at least 30 days post-discharge enrollment in FFS Medicare
- 2. Discharged against medical advice (AMA)
- 3. Admissions for subsequent qualifying CABG procedures during the measurement period

De.1. Measure Type: Outcome

S.17. Data Source: Claims, Enrollment Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Dec 23, 2014 Most Recent Endorsement Date: Jul 12, 2017

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 not formally paired with another measure, however it is harmonized with a measure of hospital-level, all-cause, 30-day, risk-standardized mortality following a qualifying isolated CABG procedure.

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.

Criteria 1: Importance to Measure and Report

1a. Evidence

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 2017

- During the last review in 2017, the developer did not provide new evidence for consideration. Based on the developer's prior submission of evidence in 2015, the Standing Committee agreed to pass the measure on this criterion.
- The developer provides a <u>logic model</u> depicting the risk of readmission which research showed can be influenced by the quality of care provided within the health system and, specifically, that interventions such as improved discharge planning, reconciling patient medications, and improving communications with outpatient providers can reduce readmission rates.

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 stated that CABG is a priority area for outcome measure development because it is a common procedure associated with considerable morbidity, readmissions, mortality, and healthcare spending.
- The developer reported that acute myocardial infarction and coronary atherosclerosis, which are often treated by CABG procedures, represent the 5th and 9th most costly conditions in the US across all ages and payers respectively, despite being relatively less common reasons for inpatient admission; the ranking for these conditions rises among patients 65 years and older.
- The developer shared data from the Massachusetts Data Analysis Center from fiscal year 2014 stating that isolated CABG surgeries accounted for almost half (40.59%) of all cardiac surgery hospital admissions in Massachusetts. In 2014, the developer reported that the average Medicare payment was \$32,499 for CABG without valve and \$45,873 for CABG plus valve surgeries.
- The developer cited that that though there have been advancements over the last two decades in the management of coronary artery disease and therefore a subsequent decline in CABG procedures and readmissions, considerable variation in CABG readmission rates suggests that there is still room for quality improvement; notably, for the time period of July 2015-June 2018, publicly reported 30-day risk-standardized readmission rates ranged from 9.3% to 22.1% for Medicare fee-for-service (FFS) patients undergoing isolated CABG surgery.
- The developer reported findings that show current hospital interventions can decrease risk of readmission, but 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.

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

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

Maintenance measures - increased emphasis on gap and variation

<u>1b. Performance Gap.</u> The performance gap requirements include demonstrating quality problems and opportunity for improvement.

• The developer provided data showing variation in readmission rates in data from July 1, 2016 to June 30, 2019 Medicare claims data (n=131,592 admissions from 1,160 hospitals) and Veterans Affairs (VA) administrative data. The three-year hospital-level risk standardized readmission rates (RSRRs) have a mean of 12.8% and a range of 8.6% - 22.6% in the study cohort. The median RSRR is 12.7%.

Disparities

- The developer provided data from Medicare fee-for-service (FFS) claims and Master Beneficiary Summary File (MBSF) from July 2016 through June 2019 showing the 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 12.5%, whereas hospitals with a higher proportion of dual eligible patients (forth quartile) had a median performance of 13.1%.
- The developer provided data from Medicare FFS claims and The American Community Survey (2013-2017) data from July 2016 through June 2019 showing the variation in RSRRs across hospitals (with at least 25 cases) by proportion of patients with social risk in lower and upper social risk quartiles. Hospitals with a lower proportion of patients with Agency for Healthcare Research & Quality Socioeconomic Status (AHRQ SES) index scores (first quartile) had a median performance of 12.6%, whereas hospitals with a higher proportion of patients with AHRQ SES index scores (forth quartile) had a median performance of 12.9%.

Questions for the Committee:

• Is the gap in care significant enough to warrant a national performance measure?

Preliminary rating for opportunity for improvement:	🛛 High	🛛 Moderate	🗆 Low	Insufficient
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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
- No concerns
- Evidence to support not aware of any new studies that change the evidence
- 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

 There is an abundance of evidence that explores CABG outcomes including readmission rates following operations. There is also a significant variation in readmission rates for CABG (a presumed standard operation). Readmission rates add to costs and amplify postoperative complication rates.

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 11.2-13.6, 2.4 percentage point diff, ~15% diff
- No concerns
- Current performance data provided and AHRQSES index scores utilized
- 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 demonstrated a gap in care and need for a national performance measure. Dual eligible status and AHRQ SES index was used to measure social risk factors (SFRs).
- There is a significant variation in CABG readmission rates after operation ranging between 9% and 22% of discharged patients. Many of these readmissions seem to be related to coordinated transitions to home environments.

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? \boxtimes Yes \square No

Evaluators: NQF Scientific Methods Panel

SMP Rating:

R: H-1; M-7; L-1; I-0 (Pass) V: H-1; M-5; L-3; 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, Master Beneficiary Summary File data from 2013-2019 and the Society of Thoracis Surgeons (STS) Cardiac Surgery Database at the facility 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). The facility-level reliability testing was limited to facilities with at least 25 admissions for public reporting.

• Reliability testing results:

- Signal-to-noise reliability testing:
 - The developer reported signal-to-noise reliability scores ranging from 0.27 to 0.92, with a mean and median of 0.60, mean of 0.58, and an interquartile range of 0.45 and 0.71, respectively. The median signal to noise scores demonstrates substantial agreement.
 - An ICC of 0.436 was calculated using a split sample (i.e., test-retest) method. This value represents the lower bound of estimate of the true measure reliability.

Validity

- Empirical Validity
 - The developer examined the relationship between the performance of COPD RSRR to that of Hospital Star Rating Readmission group scores, Hospital CABG Surgical Volume, and the Overall Hospital Star Ratings.
 - The correlation between CABG RSRRs and:
 - Star-Rating readmissions score is -0.307, which led the developer to suggest that hospitals with lower CABG RSRRs are more likely to have higher Star-Rating readmission scores.
 - Star-Rating summary score is -0.238, which the developer suggests that hospitals with lower CABG RSRRs are more likely to have higher Star-Rating summary scores.
 - Hospital CABG admission volume among hospitals with more than 25 CABG admissions show mean RSRRs slightly lower among high volume hospitals compared to lower volume hospitals.
- Face Validity as Determined by a developer-convened technical expert panel (TEP)
 - The TEP consisted of 11 members, who were tasked to assess the face validity of the measure score as an indicator of quality.
 - The developer solicited the TEP members' agreement with the following statement: "The readmission rates obtained from the readmission measure as specified will provide an accurate reflection of quality". 71% of TEP members agreed (somewhat, moderately, or strongly) that the measure will provide an accurate reflection of quality.
- Risk adjustment Summary:
 - The measure developer utilized a statistical risk model with 26 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 AHRQ SES index and dual eligibility variables. The developer states that they aim to capture the social risk factors (SRFs) 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. There was only a small effect on a multivariable model when adding these SRFs.
 - The developer reports that in 2020, dual-eligibility and the AHRQSES index have odds ratios of 1.32 and 1.13 when added independently to the model. Furthermore, the effect size of each variable is attenuated (1.29 and 1.10 for dual and SES) when both are added to the model.

Questions for the Committee regarding reliability:

- The Standing Committee should discuss the reliability testing results, including the results of the lower tail of the reliability inter-quartile range.
- Does the Standing Committee 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 Standing Committee think there is a need to discuss and/or vote on reliability?

Questions for the Committee regarding validity:

- Does the Standing Committee have any concerns regarding the validity of the measure (e.g., exclusions, risk-adjustment approach, etc.)?
- The Standing 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 Standing 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
- 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
- Research suggests that discharge planning and improved communication with local physicians are key elements of limiting CABG readmissions. It might be difficult to define measures taken to facilitate transitions and to account for all measures that are taken after patients leave hospital after operations, since these transition steps are not always documented in discharge records.

2a2. Reliability - Testing: Do you have any concerns about the reliability of the measure?

- Yes. Split sample 0.436 median s/n 0.60. Low in terms of differentiating. Of 992 hospitals with enough cases to include, only 6 are identified as better than national, 14 worse.
- No concerns
- No concerns
- No
- No. Two types of reliability testing was done.
- The reliability should be excellent since there is a well-defined patient population undergoing a fairly standard operation with very predictable outcomes.

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

- No
- No concerns
- No concerns
- No
- No
- The Authors used a test sample and a validation sample to test measure validity. This seems very appropriate.

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 0.64 model has some but not substantial differentiation.
- No concerns
- Used AHRQ SES index and duel eligible
- Yes
- Social risk factors were analyzed using dual eligible and AHRQSES data
- Risk adjustment is rigorous and involves a robust risk assessment and stratification, based at least partially on administrative data on each patient for the 12 months prior to the index admission and on multiple elements of the Medicare database.

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 concerns
- No concerns
- No
- No concerns. Relationship between CABG RSRRs and other quality measures; Hospital Star Rating readmission group score, Overall Hospital Star and Hospital CABG Surgical Volume Rating correlation to COPD RSRRs were used to establish validity were examined

• The Authors acknowledge the potential for bias related to social risk factors. They accounted for some important socioeconomic risk factors and area deprivation indices in their analysis. This represents a novel undertaking that may prove to be very important in determining readmission rates.

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

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 concerns
 - Use claims data--feasibility
 - None
 - No concerns. The measure uses data already collected by hospitals
 - The majority of data elements are readily available from Medicare and other databases.

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

Current use in an accountability program? \square Yes \square No \square 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 three years as a part of comprehensive reevaluation as mandated by the Measure Management System Blueprint.
- Each year, issues raised through direct questions & answers 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 Inpatient Prospective Payment System or other rule.
- Several requests and questions about specifications, interpretation of results and measure implementation 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:	\boxtimes	Pass	🛛 No Pass
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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 reported that the median hospital 30-day, all-cause, RSRR for the CABG readmission measure for the three-year period between July 1, 2016 and June 30, 2019 was 12.7%. They stated that the median RSRR decreased by 0.6 absolute percentage points from July 2016-June 2017 (median RSRR: 12.9%) to July 2018-June 2019 (median: RSRR: 12.3%).

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

Potential harms

• The developer did not report any unexpected findings.

Additional Feedback:

• 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?
- Do the benefits of the measure outweigh any potential unintended consequences?

Preliminary rating for Usability and use: 🛛 High 🗌 Moderate 🔲 Low 🔲 Insufficient

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 concerns
- Yes usable and currently being used
- Yes
- Current use on various publicly available websites including Hospital Compare and Hospital Readmission Reduction Program. Feedback was reviewed. No changes made to measure
- There does not seem to be a mechanism for feedback incorporated into the proposal. There is no provision for feedback from patients having readmissions.

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.

- Some small evidence of improvement between 2016-1019 but biggest improvements at better than average performance, not reduction from high readmission rates
- No concerns
- No harm noted
- The benefits outweigh any unintended consequences
- No harm identified. Benefit in reducing hospital readmissions

• Performance results can be used to amplify efforts at limiting post-CABG readmissions. There are no obvious harms associated with this type of analysis. Benefits would likely accrue to future patients, not necessarily to the studied patients.

Criterion 5: Related and Competing Measures

Related or competing measures

- 0114 : Risk-Adjusted Postoperative Renal Failure
- 0115 : Risk-Adjusted Surgical Re-exploration
- 0119 : Risk-Adjusted Operative Mortality for CABG
- 0129 : Risk-Adjusted Postoperative Prolonged Intubation (Ventilation)
- 0130 : Risk-Adjusted Deep Sternal Wound Infection
- 0131 : Risk-Adjusted Stroke/Cerebrovascular Accident
- 0330 : Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following heart failure (HF) hospitalization
- 0505 : Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following acute myocardial infarction (AMI) hospitalization.
- 1789 : Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)
- 2558 : Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following coronary artery bypass graft (CABG) surgery
- 3494 : Hospital 90-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery

Harmonization:

- The developer reported that the measure is harmonized with the above measures to the extent possible given the different data sources used for development and reporting.
- The developer stated that the CABG readmission measure was developed in close collaboration with STS. It was developed concurrently with a clinical registry data-based readmission measure (Risk-adjusted readmission measure for coronary artery bypass graft (CABG)). The exclusions are nearly identical to the STS measures' cohort exclusions with the exception of epicardial MAZE procedures; STS excludes these procedures from the registry-based CABG readmission measure cohort because the version of registry data used for measure development did not allow them to differentiate them from open maze procedures. STS measures are specified for age 18 and over, and the CABG readmission measure is currently specified for age 65 and over.
- The STS cardiac surgery registry currently enrolls most, but not all, patients receiving CABG surgeries in the US. The proposed CABG readmission measure will capture all qualifying Medicare FFS patients undergoing CABG regardless of whether their hospital or surgeon participates in the STS registry. This claims-based CABG readmission measure was developed with the goal of producing a measure with the highest scientific rigor and broadest applicability.

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
- No concerns

- Measure harmonized with noted measures
- Yes and they are harmonized to the extent possible
- There are competing measures but the developer noted they differ in the data sources used for developing measures. Harmonization done to furthest extent
- There are other related readmission measures included in the NQF portfolio, but the current measure applies to a very well-defined population (post-op CABG). This fact distinguishes this metric others with less well defined patient populations.

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 #2515, Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery. We are disappointed to see the minimum measure score reliability results of 0.27 and the intraclass correlation coefficients (ICC) was 0.436 using a minimum case number of 25 patients. We believe that measures must meet minimum 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 not include 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 6 hospitals performed better than the national rate and 14 hospitals 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 0.6 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> <u>purchasing-programs</u>

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 coronary artery bypass graft (CABG) surgery. The FAH is concerned that even though the median reliability score was 0.60 for hospitals with at least 25 cases, reliability ranged from 0.27 to 0.92 and that the intraclass correlation coefficients (ICC) was 0.436. 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 recommendational 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 6 hospitals identified as better than the national rate and 14 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 0.6 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 I support this measure.
- Of the 1 NQF member who have submitted a support/non-support choice:
 - 1 supports the measure
 - 0 do not support the measure

Combined Methods Panel Scientific Acceptability Evaluation

Scientific Acceptability: Preliminary Analysis Form

Measure Number: 2515

Measure Title: Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery **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

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

Panel Member #5 NOTE: There are several references to "clinical registry data" in the MIF document, but the Registry Data box is not checked in their NQF Testing document.

Level of Analysis:

 \Box Clinician: Group/Practice \Box Clinician: Individual \boxtimes Facility \Box Health Plan

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

□ Integrated Delivery System □ Other

Measure is:

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.

2. Briefly summarize any concerns about the measure specifications.

Panel member #1 NONE

Panel Member #4 None

Panel Member #8 No concerns about the specs.

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 Overall measure score reliability was estimated by calculating the intra-class correlation coefficient (ICC) using a split sample (i.e. test-retest) method, the facility-level reliability was assessed through signal-to-noise reliability.

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

Panel Member #4 Developer used both split sample and signal-to-noise

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 Measure score reliability was assessed by split-sample reliability and by signal-to-noise. **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 0.436

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 0.60

S/N: 10th percentile 0..35

S/N: 90th percentile 0.71

Out of 1,160 hospitals in the measure cohort, 6 performed "better than the U.S. national rate," 972 performed "no different from the U.S. national rate," and 14 performed "worse than the U.S. national rate." 168 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 11.1-14.3, a 3.2 percentage point difference. Given the number of cases, this is clinically meaningful.

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 to marginal 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 (20 of 992, 2 percent) identified as performing better than or worse than the national rate.

These data show a marked difference between the statistics of the split sample and signal to noise. The S/N at 0.6 median is below the 0.70 reference in Adams but not too differentiated. The 0.436 split sample correlation is well below the level I would consider reliable for individual scoring.

Reliability might be improved if the minimum number of cases was substantially raised for the indicator. (This is a general comment with some applicability across all the measures with low reliability.

Panel Member #2 Signal-to-noise reliability score for each hospital with at least 25 admissions found median reliability score of 0.60, which demonstrates moderate reliability.

Split-sample analysis that used the Spearman-Brown prediction formula found the agreement between the two independent assessments of the RSRR for each hospital to be 0.436, indicating moderate reliability.

Panel Member #3 It is concerning that the signal-to-noise ratio is 0.44 or less for 25 percent of hospitals. I wonder if the minimum case volume per hospital is too low? The median is 0.60, which is better than some of the readmissions measures in this set. That said, the ICC for the test-retest is 0.436.

Panel Member #4 Using a minimum case volume of 25 the measure had moderate reliability. **Panel Member #6** Split-Sample Reliability: A total of 131,592 admissions were included in the analysis based on 3 years of data. After randomly splitting the sample into two halves, there were 65,497 admissions from 1,134 hospitals in one half and 66,095 admissions from 1,160 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 0.436.

Signal-to-Noise: The signal-to-noise reliability score was calculated for hospitals with at least 25 admissions. The median reliability score was 0.60, ranging from 0.27 to 0.92. The 25th and 75th percentiles were 0.45 and 0.71, respectively.

The developers indicate the reliability score demonstrates moderate agreement. However, the ICC of 0.436 is at the LOWER END based on the Landis (1977) scale used. The SMP has expressed concerns about application of this scale and especially about ICC scores below .50 indicating reliable measurement of hospital level performance.

Panel Member #8 Split sample reliability yielded an intraclass coefficient of 0.436 for hospitals of at least 25 admissions.

Signal-to-noise for hospitals with at least 25 admissions had a median score of 0,60, ranging from 0.27 to 0.92. The 25th and 75th percentiles were 0.45 and 0.71.

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 **not** 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 to marginal 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 (20 of 992, 2 percent) identified as performing better than or worse than the national rate.

These data show a marked difference between the statistics of the split sample and signal to noise. The S/N at 0.6 median is below the 0.70 reference in Adams but not too differentiated. The 0.436 split sample correlation is well below the level I would consider reliable for individual scoring.

Reliability might be improved if the minimum number of cases was substantially raised for the indicator. (This is a general comment with some applicability across all the measures with low reliability. **Panel Member #2** See 6 and 7 above

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 **Panel Member #5** Reliability testing was adequate. The signal to noise value is adequate, but is this value derived based on the >= 65 or >= 18 population; text is not clear.

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 0.436 and 0.60, indicating 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 "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.

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

Panel Member #8 Both signal-to-noise and split-sample results indicated moderate reliability.

Panel Member #9 Demonstrated substantial agreement for measure score reliability

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 Only 994 hospitals seemed to have the qualifying CABG admissions. Then why not included this as an exclusion criterion.

Panel Member #4 None

Panel Member #6 None.

Panel Member #8 The exclusions are common to Medicare claims data.

Less than 0.5% of patients were excluded, the major reason being without at least 30 days post-discharge enrollment in FFS Medicare.

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 6 or 0.60% (better) and 14 or 1.41% (worse) were outliers when compared to the US national rate. Thus, I just wonder if the measure is truly identifying meaningful difference in quality between hospitals.

Panel Member #3 None

Panel Member #4 None

Panel Member #6 The developers report a median odds ratio of 1.23 which they say suggests a meaningful increase in the risk of readmission if a patient is admitted with CABG at a higher risk hospital compared to a lower risk hospital. A ratio indicates that a patient has a 23% 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 for CABG. However, the distribution of rates is not shown, such as differences in rates across deciles or quartiles. They did report the range of RSRRS in the testing dataset was 8.6% to 22.6%. I would like to see more data on the distribution of rates to better understand whether the measure can truly identify "meaningful differences" in performance between hospitals.

Panel Member #8 After estimating the 95% interval estimate, those that include the national rate are designated as "no different than the national rate", while those that do not include the national rate are either better or worse than the national rate.

The results show that of 1,160 hospitals 6 performed "better than" the national rate, 972 performed "no different from" the national rate, 14 performed "worse than" the national rate, and 168 had too small of volumes to classify. The median odds ratio was 1.23, which means the patient admitted to a higher risk hospital has a 23% higher chance of readmission than one admitted to 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 guite 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 NA Panel Member #4 None Panel Member #8 The is no missing data. Panel Member #9 N/A 16. Risk Adjustment Statistical model – Panel Member #6 26 16a. Risk-adjustment method □ None risk factors **Stratification** 16b. If not risk-adjusted, is this supported by either a conceptual rationale or empirical analyses? 🛛 Yes 🗆 No \boxtimes Not applicable 16c. Social risk adjustment: \boxtimes No \square Not applicable 16c.1 Are social risk factors included in risk model? 🛛 Yes Panel Member #5 ZIP code level—Area Deprivation Index (ADI) from Census data (2009-2013) 16c.2 Conceptual rationale for social risk factors included? Xes □ No 16c.3 Is there a conceptual relationship between potential social risk factor variables and the measure focus? \boxtimes Yes □ No 16d. Risk adjustment summary: 16d.1 All of the risk-adjustment variables present at the start of care? 🛛 Yes 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? \boxtimes 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) 🛛 Yes 🗆 No 16d.5. Appropriate risk-adjustment strategy included in the measure? \boxtimes Yes □ No Panel Member #5 See previous comments 16e. Assess the risk-adjustment approach Panel Member #1 Risk adjustment approach is standard CMS HCC model. C-stat of 0.64 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 >0.98.

Panel Member #2 One concern is the C-statistic of the base model which is 0.64. This low C-statistic suggest the model may not be a good fit to the data at hand.

Panel Member #3 The logistic regression model fit is modest (0.64), 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 CABG (e.g., end of life, frailty variables such as pressure ulcers, cancers, stroke, CKD). This resulted in a final risk adjustment model with 26 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 SFF 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 SFR variables however showed disparities in readmission rates; 2020 observed rate for dual eligible patients was 19.2% (compared to only 12.3% for non-duals), and for patients with low AHRQ SES scores 14.8% (compared to 12.3% 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 1.29 and 1.10 when added independently into the model. *NOTE that these ORs are actually LARGER than the 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 0.037% (interquartile range [IQR] -0.023% - 0.047%) 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 0.139% (IQR -0.117% - 0.153%) with a correlation coefficient between RSRRs for each hospital with and solute change in hospitals' RSRRs when adding a low AHRQ SES Index score indicator to the model was 0.139% (IQR -0.117% - 0.153%) 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 0.981.

The contextual effect analysis of patient level vs. hospital level effects of the SRFs showed both the patient-level and hospital-level dual eligibility, as well as low AHRQSES Index effects, were significantly associated with CABG readmissions in the decomposition analysis. They claim that *"the significance of the hospital-level effects indicates that if dual eligibility or low AHRQSES Index variables were used 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."* 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 dual status effect was much larger at patient level than hospital level based on 2020 parameter estimates.

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 An expert panel reviews the Condition Categories and removes those that are not applicable to this measure. Then, the remaining variables are analyzed by stepwise logistic regression to derive those most statistically associated with the outcome. Finally, the expert panel reviews the final list to ensure appropriateness for inclusion.

Social risk factors were included in the model but did not outweigh or contribute significantly to the model performed once hospital-based variables were included.

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 with STAR ratings readmission score

Correlation with STAR ratings overall score

Correlation with CABG volume

Panel Member #2 Validity was sought to be assessed through the correlation of CABG RSRR and the following three measures: Hospital Star Rating readmission group score (hypothesized relationship:

negative); Overall Hospital Star Rating (hypothesized relationship: negative) and Hospital CABG Surgical Volume (hypothesized relationship: negative)

Panel Member #4 Construct validity demonstration was attempted using both measures with a similar construct and volume.

Panel Member #3 The measure developers focus on validity using three measures from hospitals compare. I expect to see the strongest correlation between CABG readmissions and the Hospital CABG Surgical Volume measure.

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, the Overall Hospital Star Rating, and the Hospital CABG Surgical Volume. They also assessed validity based on responses from the technical expert panel.

They conducted further tests of validity of the measure cohort and model as assessed by Registry Data Validation in collaboration with the Society of Thoracic Surgeons Adult Cardiac Surgery Database, including validation of the administrative cohort to the registry CABG cohort. They validated the model by comparing the hospital-level RSRRs to those calculated by the STS clinical data-based CABG readmission measure.

Panel Member #8 Empirical validity testing was based on correlation with three other

measures: the Hospital Star Rating Group Score, the Overall Hospital Star Rating, and the Hospital CABG Surgical Volume. The first association had a correlation of -0.307, the second one -0.238.

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 -.307

Correlation with STAR ratings overall score: -.238

Correlation with volume -0.135

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

Panel Member #2 The correlation between CABG RSRR and Hospital Star Rating readmission group score was -0.307

The correlation between CABG RSRR and overall Hospital Star was -0.238

The correlation between CABG RSRR and Hospital CABG Surgical Volume was -0.135

Thus, the all of the hypothesized relationships were established, suggesting the empirical validity of this measure.

Panel Member #3 I was a little disappointed to see that correlation the CABG volume measure was only -0.13. The strongest correlation was with the readmissions measure group (.307) – I suppose this makes sense since this is a readmission measure. Would be great to see some predictive validity here. **Panel Member #4** The demonstration of an implicitly quality construct only is a low rating. When

an explicitly construct was used (volume) the relationship was minimal

Panel Member #5 The measure has been widely used by many researchers in published articles. **Panel Member #6** Correlation between CABG RSRRs and Star-Rating readmissions score was -0.307, indicating hospitals with lower readmission rates were only slightly more likely to have higher Star-Rating readmission scores as expected. The correlation between CABG RSRRs and the Overall Star-Rating summary score was -0.238, which suggests that hospitals with lower CABG RSRRs are *only slightly more likely* to have higher Star-Rating summary scores as expected. The correlation of the latter was hypothesized to be lower at the Overall Star Rating is influenced by many other measures. The relationship between CABG RSRRs and hospital CABG admission volume results show that mean RSRRs are very marginally lower among high volume hospitals compared to lower volume hospitals (mean rates at lowest volume decile were 12.89 compared to mean rates at the highest volume decile of 12.27). The face validity results were not presented. The results of the other validation against the STS data were also not presented as far as I can tell.

Overall, these results support relatively low measure score validity.

Panel Member #8 The associations with other measures of quality were moderate and negatively correlated as expected. Volume by deciles generally trended towards lower readmission rates, but across the 10% decile to the 90th decile was a difference of 12.89 mean RSRR to 12.27 mean RSRR.

Panel Member #9 Moderate correlation of CABG 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)
- \boxtimes **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.

Panel Member #1 Measure has face validity and reasonable correlation with other similar measures. **Panel Member #2** Seem my explanations in 16e, 21, and 22 above.

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

Panel Member #4 The rating of low is based on both the method and the result

Panel Member #5 Developer demonstrated an effort to risk adjust measure to create valid measure score. Very low inter-decile distribution across Providers (3.2% between 10th and 90th 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 \geq 65 vs. \geq 18 was tested, although results were unclear. For example, was the distribution of percentile values based on the >= 18 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 CABG 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. 13.0 and median Q4 = approx. 12.5, despite low correlations across the quartiles. Additionally, the RSRR value decile distribution for hospitals with higher or lower CABG admissions show virtually no difference (12.89 for lowest admission decile to 12.27 for

highest admission decile). Is this measure really producing any differences in the quality of performance over the past several years?

Panel Member #6 The validity test results show relatively low validity of the model. The missing TEP face validity results are curious.

Panel Member #7 "Therefore, the results above show that the trend and results of the CABG readmission measure are in agreement with other measures of similar quality. Additionally, this validation approach compared various categories and deciles of hospital CABG admission volume with CABG readmission measure scores in Table 3 – these results demonstrate an observed trend of higher hospital volume with lower readmission rates, especially in hospitals with the largest volumes."

Panel Member #9 The QM Stewards demonstrated moderate validity using a unique correlation between the CABG RSRR and the Star Ratings. The addition of the Association between CABG RSRRs and Hospital CABG Admission Volume added support of validation which is why I rated this one high vs the other readmission measures

FOR COMPOSITE MEASURES ONLY: Empirical analyses to support composite construction

27. 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

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

ADDITIONAL RECOMMENDATIONS

29. 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 #1 Given low reliability, one issue is whether to recommend higher minimum case numbers for use with the measure.

Panel Member #6 See comments related to evaluating the risk adjustment findings related to social risk factors.

NQF #: 2515

Corresponding Measures:

De.2. Measure Title: Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery

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

De.3. Brief Description of Measure: The measure estimates a hospital-level risk-standardized readmission rate (RSRR), defined as unplanned readmission for any cause within 30-days from the date of discharge for a qualifying index CABG procedure, in patients 65 years and older.

An index admission is the hospitalization for a qualifying isolated CABG procedure considered for the readmission outcome.

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 CABG surgery are influenced by complex and critical aspects of care, such as: communication between providers; prevention of, and response to, complications; patient safety; 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 measure was developed to identify institutions whose performance is better or worse than would be expected based on each institution's 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 a qualifying isolated CABG procedure, CABG readmissions are a priority area for outcome measure development. 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 readmissions. We define readmission as an inpatient acute care admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index admission for an isolated CABG surgery in patients 65 and older. If a patient has more than one unplanned admission (for any reason) within 30 days after discharge from the index admission. 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 who are age 65 and older with a qualifying isolated CABG procedure and complete claims history for the 12 months prior to the index admission.

S.8. Denominator Exclusions: For all cohorts, hospitalizations are excluded if they meet any of the following criteria, for admissions:

- 1. Without at least 30 days post-discharge enrollment in FFS Medicare
- 2. Discharged against medical advice (AMA)

3. Admissions for subsequent qualifying CABG procedures during the measurement period

De.1. Measure Type: Outcome

S.17. Data Source: Claims, Enrollment Data

S.20. Level of Analysis: Facility

IF Endorsement Maintenance – Original Endorsement Date: Dec 23, 2014 Most Recent Endorsement Date: Jul 12, 2017

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 not formally paired with another measure, however it is harmonized with a measure of hospital-level, all-cause, 30-day, risk-standardized mortality following a qualifying isolated CABG procedure.

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_CABGreadmission_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): 2515

Measure Title: Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery

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: 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery

□ 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. CABG 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 care
- Encouraging strategies that promote disease management



 Improving health status
 Improved healthcare support and 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 coronary artery bypass graft (CABG) surgery. 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; and 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.

CABG is a priority area for outcome measure development because it is a common procedure associated with considerable morbidity, readmissions, mortality, and health care spending. Acute myocardial infarction and coronary atherosclerosis, which are often treated by CABG procedures, represent the 5th and 9th most costly conditions in the US across all ages and payers respectively, despite being relatively less common reasons for inpatient admission; the ranking for these conditions rises among patients 65 years and older (Torio et al., 2016). In fiscal year 2014, isolated CABG surgeries accounted for almost half (40.59%) of all cardiac surgery

hospital admissions in Massachusetts (Massachusetts Data Analysis Center, 2014). In 2014, the average Medicare payment was \$32,499 for CABG without valve and \$45,873 for CABG plus valve surgeries (Drye et al., 2009; Pennsylvania Health Care Cost Containment Council, 2014).

Although there have been advancements over the last two decades in the management of coronary artery disease and therefore a subsequent decline in CABG procedures and readmissions (McNeely et al., 2017; Weiss et al., 2014), considerable variation in CABG readmission rates suggests that there is still room for quality improvement; notably, for the time period of July 2015-June 2018, publicly reported 30-day risk-standardized readmission rates ranged from 9.3% to 22.1% for Medicare fee-for-service (FFS) patients undergoing isolated CABG surgery (Wallace et al., 2019). Although many current hospital interventions are known to decrease the risk of readmission within 30 days of hospital discharge, 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.

Furthermore, research on a variety of conditions and procedures has shown that readmission rates are influenced by the quality of care provided within the health system and, specifically, that interventions such as improved discharge planning, reconciling patient medications, and improving communications with outpatient providers can reduce readmission rates. A number of recent studies have demonstrated that improvements in care at the time of patient discharge can reduce 30-day readmission rates (Naylor et al., 1994, 1999; Krumholz et al., 2002; van Walraven et al., 2002; Conley et al., 2003; Coleman et al., 2004; Philips et al., 2004; Jovicic et al., 2006; Garasen et al., 2007; Mistiaen et al., 2007; Courtney et al., 2009; Koehler et al., 2009; Jack et al., 2009; Weiss et al., 2010; Stauffer et al., 2011; Voss et al., 2011, Williams et al., 2011; Bates et al., 2014).

References:

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Voss R, Gardner R, Baier R, Butterfield K, Lehrman S, Gravenstein S. The care transitions intervention: translating from efficacy to effectiveness. *Archives of Internal Medicine*. Jul 25 2011;171(14):1232-1237.

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

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? 	*

Systematic Review	Evidence
Estimates of benefit and consistency across studies	*
What harms were identified?	*
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.

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 CABG surgery are influenced by complex and critical aspects of care, such as: communication between providers; prevention of, and response to, complications; patient safety; 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 measure was developed to identify institutions whose performance is better or worse than would be expected based on each institution's 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 a qualifying isolated CABG procedure, CABG readmissions are a priority area for outcome measure development. 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 data (n=131,592 admissions from 1,160 hospitals). As shown below, the three-year hospital-level risk standardized readmission rates (RSRRs) have a mean of 12.8% and a range of 8.6% - 22.6% in the study cohort. The median RSRR is 12.7%. The distribution of RSRRs across hospitals is shown below:

Distribution of Hospital CABG 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//1,135//1,114//1,091//1,160

Number of Admissions//44,306//44,009//43,277//13,1592

Mean(SD)//12.9(0.7)//12.9(1)//12.3(1)//12.8(1.3)

Range(Min-Max)//10.3-17.2//9.8-18.8//8.7-17.2//8.6-22.6

Minimum//10.3//9.8//8.7//8.6

```
10th percentile//12.1//11.8//11.2//11.1
```

20th percentile//12.4//12.2//11.6//11.7

30th percentile//12.6//12.5//11.8//12.1

40th percentile//12.7//12.7//12.1//12.5

50th percentile//12.9//12.9//12.3//12.7

60th percentile//13.0//13.1//12.5//13.0

70th percentile//13.2//13.3//12.8//13.3

80th percentile//13.4//13.6//13.1//13.8

90th percentile//13.7//14.1//13.6//14.3

Maximum//17.2//18.8//17.2//22.6

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 CABG RSRRs by Proportion of Dual Eligible Patients:

Data source: Medicare FFS claims and Master 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(%)//(0-7.96)//(24.44-84.38) # of Hospitals//248//248 100% Max//17.5//22.6 90%//14.2//14.8 75%//13.4//14.0 50%//12.5//13.1 25%//11.7//12.1 10%//10.8//11.5 0% Min//8.7//9.5 Distribution of 30-day CABG RSRRs by Proportion of Patients with AHRQ SES Index Scores: Data source: Medicare FFS claims 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(%)//(0-2.52)//(7.73-82.28) # of Hospitals//248//247 100% Max//18.6//17.9 90%//14.4//14.6 75%//13.5//13.7 50%//12.6//12.9 25%//11.6//12.0 10%//10.9//11.4 0% Min//8.6//9.6

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):

Cardiovascular, Cardiovascular : Coronary Artery Disease, Surgery : Cardiac Surgery

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

Care Coordination, Care Coordination : Readmissions, Care Coordination : Transitions of Care, Safety : Complications, Safety : Healthcare Associated Infections

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://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_CABGreadmission_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 readmissions. We define readmission as an inpatient acute care admission for any cause, with the exception of certain planned readmissions, within 30 days from the date of discharge from the index admission for an isolated CABG surgery in patients 65 and older. 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 after undergoing isolated CABG surgery, excluding planned readmissions as defined below. Although clinical experts agree that planned readmissions are rare after CABG, they likely do occur. Therefore, to identify these planned readmissions we have adapted and applied an algorithm originally created to identify planned readmissions for a hospital-wide (i.e., not condition-specific) readmission measure.

Planned Readmission Algorithm (Version 4.0)

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

In brief, the algorithm identifies a short list of always planned readmissions (those where the principal discharge diagnosis is major organ transplant, obstetrical delivery, or maintenance chemotherapy) as well as those readmissions with a potentially planned procedure (e.g., total hip replacement) AND a non-acute principle discharge diagnosis code. For example, a readmission for colon resection is considered planned if the principal diagnosis is colon cancer but unplanned if the principal diagnosis is abdominal pain, as this might represent a complication of the CABG procedure or hospitalization. Readmissions that included potentially planned procedures with an acute principal diagnosis or procedures that might represent specific complications of CABG, such as PTCA or repeat CABG are not excluded from the measure outcome as they are considered unplanned in this measure.

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 CABG measure with modifications.

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

It should be noted that this approach differs from that adopted by STS for their registry-based measure, in which all 30-day readmissions were considered to be unplanned.

Outcome Attribution

Attribution of the outcome in situations where a patient has multiple contiguous admissions, at least one of which involves an index CABG procedure (i.e., the patient is either transferred into the hospital that performs the index CABG or is transferred out to another hospital following the index CABG) is as follows:

- If a patient undergoes a CABG procedure in the first hospital and is then transferred to a second hospital where there is no CABG procedure, the readmission outcome is attributed to the first hospital performing the index CABG procedure and the 30-day window starts with the date of discharge from the final hospital in the chain.

Rationale: A transfer following CABG is most likely due to a complication of the index procedure and that care provided by the hospital performing the CABG procedure likely dominates readmission risk even among transferred patients.

 If a patient is admitted to a first hospital but does not receive a CABG procedure there and is then transferred to a second hospital where a CABG is performed, the readmission outcome is attributed to the second hospital performing the index CABG procedure and the 30-day window starts with the date of discharge from the final hospital in the chain.

Rationale: Care provided by the hospital performing the CABG procedure likely dominates readmission risk.

- If a patient undergoes a CABG procedure in the first hospital and is transferred to a second hospital where another CABG procedure is performed, the readmission outcome is attributed to the first hospital performing the index (first) CABG procedure and the 30-day window starts with the date of discharge from the final hospital in the chain.

Rationale: A transfer following CABG is most likely due to a complication of the index procedure, and care provided by the hospital performing the index CABG procedure likely dominates readmission risk even among transferred patients.

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

The cohort includes admissions for patients who are age 65 and older with a qualifying isolated CABG procedure and complete claims history for the 12 months prior to the index admission.

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).

In order to create a clinically coherent population for risk adjustment, and in accordance with existing NQFapproved CABG measures and clinical expert opinion, the measure is intended to capture isolated CABG patients (i.e., patients undergoing CABG procedures without concomitant valve or other major cardiac or vascular procedures).

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

For all cohorts, hospitalizations are excluded if they meet any of the following criteria, for admissions:

- 1. Without at least 30 days post-discharge enrollment in FFS Medicare
- 2. Discharged against medical advice (AMA)
- 3. Admissions for subsequent qualifying CABG procedures during the measurement period

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.)

The CABG readmission measure excludes hospitalizations if they meet any of the following criteria:

1. Without at least 30 days post-discharge enrollment in FFS Medicare

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. Discharged 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. Admissions for subsequent qualifying CABG procedures during the measurement period.

Rationale: CABG procedures are expected to last for several years without the need for revision or repeat revascularization. A repeat CABG procedure during the measurement period likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery. Therefore, we select the first CABG surgery admission for inclusion in the measure and exclude subsequent CABG surgery admissions from the cohort.

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 isolated CABG surgery 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 index admission using age, sex, selected clinical covariates, and a hospital-specific intercept. At the hospital level, it models the hospital-specific intercept 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.

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

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.

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_CABGreadmission_Fall2020_final_11.02.20-637419147547622773.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 Number (if previously endorsed): 2515

Measure Title: Hospital 30-day, all-cause, unplanned, risk-standardized readmission rate (RSRR) following coronary artery bypass graft (CABG) surgery

Date of Submission: 11/3/2020

Type of Measure:

Measure	Measure (continued)
Outcome (<i>including PRO-PM</i>)	□ Composite – <i>STOP – use composite testing form</i>
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	registry
abstracted from electronic health record	abstracted from electronic health record
eMeasure (HQMF) implemented in EHRs	eMeasure (HQMF) implemented in EHRs
Souther: Medicare Enrollment Data	☑ other: Census Data/American Community Survey, Master Beneficiary Summary File, STS Cardiac Surgery Database

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, Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database, as well as the Medicare Enrollment Database (EDB). Additionally, census data were used to assess socioeconomic factors (dual eligibility variable obtained through enrollment data; Agency for Healthcare Research and Quality [AHRQ] socioeconomic status [SES] index score obtained through census data). 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
🗆 health plan	health plan
□ other:	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, acute inpatient US hospitals (including territories) that admitted Medicare FFS beneficiaries over the age of 65 for a CABG procedure are included. Between July 1, 2016 and June 30, 2019, there were 1,160 hospitals with a qualifying admission for a CABG procedure. 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

For measure development, we used three years of Medicare administrative claims data (January 2008 – December 2010). 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 three years of data (January 2008 – December 2010) into two equal samples: **the Development Dataset** and the **Internal Validation Dataset**.

Measure Testing

For analytical updates for this measure, we used three-years of Medicare administrative claims data (July 1, 2016 – June 30, 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.

Table 1. Dataset Descriptions

Dataset	Applicable Section in the Testing Attachment	Description of Dataset
Development and Validation Datasets (Medicare Fee-For-Service Administrative Claims Data)	Section 2b3 Risk Adjustment/Stratification 2b3.6. Statistical Risk Model Discrimination Statistics 2b3.7. Statistical Risk Model Calibration Statistics	Entire Cohort: Dates of Data: January 2008 – December 2010 Number of admissions = 175,891 Number of measured hospitals: 1,164 This cohort was randomly split for initial model testing. First half of split sample - Number of Admissions: 87,872 Second half of split sample - Number of Admissions: 88,019
Testing Dataset (Medicare Fee-For-Service Administrative Claims Data (July 1, 2016 – June 30, 2019)	Section 2a2 Reliability Testing Section 2b1 Validity Testing Section 2b2 Testing of Measure Exclusion Section 2b3 Risk Adjustment/Stratification 2b3.6. Statistical Risk Model Discrimination Statistics Section 2b4 Meaningful Differences	Dates of Data: July 2016 – June 2019 Number of admissions = 131,592 Patient Descriptive Characteristics: mean age = 73.5 years; % male = 73.5% Number of measured hospitals: 1,160
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 American Community Survey (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 American Community Survey.

Dataset	Applicable Section in the Testing Attachment	Description of Dataset
Master Beneficiary Summary File (MBSF)	Section 2b3: Risk adjustment/Stratification for Outcome or Resource Use Measures	Dates of Data: July 1, 2016 – June 30, 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 dual 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 ≥25 years of age with
less than a 12th grade education, percentage of people ≥25 years of age completing ≥4 years of college,
and percentage of households that average ≥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' 9-digit 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 AHRQ SES index score equal to or below 42.7 to define the lowest quartile of the AHRQ SES 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 states, and other hospitals. Am J Manag Care. May 2018; 24(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, Hernandez AF. Utility of socioeconomic status in predicting 30-day outcomes after heart failure hospitalization. Circ Heart Fail. May 2015; 8(3):473-80.

Gilman M, Adams EK, Hockenberry JM, Wilson IB, Milstein AS, Becker ER. California safety-net hospitals likely to be penalized by ACA value, readmission, and meaningful-use programs. Health Aff (Millwood). Aug 2014; 33(8):1314-22.

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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 is compared across hospitals (Rousson, Gasser, and Seifert, 2002).

For split-sample 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 a CABG procedure. 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 signalto-noise analysis)

Measure Score Reliability Results

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 0.60, ranging from 0.27 to 0.92. The 25th and 75th percentiles were 0.45 and 0.71, respectively. The median reliability score demonstrates moderate reliability.

Mean	Std Dev.	Min	5 th Percentile	10 th Percentile	25 th Percentile	Median	75 th Percentile	90 th Percentile	95 th Percentile	Max
0.58	0.16	0.27	0.31	0.35	0.45	0.60	0.71	0.79	0.83	0.92

Table 2. Signal-to-noise reliability distribution for CABG Readmission

*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.

Split-Sample Reliability

In total, 131,592 admissions were included in the analysis, using three years of data. After randomly splitting the sample into two halves, there were 65,497 admissions from 1,134 hospitals in one half and 66,095 admissions from 1,160 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 0.436.

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

Using the approach used by Adams et. al. and Yu et al., we obtained the median signal-to-noise reliability score of 0.60, which demonstrates substantial 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

The split-sample reliability score of 0.436, discussed in the previous section, represents the lower bound of estimate of the true measure reliability.

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.

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

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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

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 CABG 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.

- 1. 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, and timeliness of care). The readmission group is comprised of the readmission measures that are publicly reported on Hospital Compare, including this measure. 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 1,160 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Rating can be found at: https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources.
- 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, and 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 1,160 Medicare FFS hospitals from July 2019. The full methodology for the Overall Hospital Star Rating can be found at https://www.qualitynet.org/inpatient/public-reporting/overall-ratings/resources.

3. Hospital CABG Surgical Volume: There is evidence that readmission rates for providers (both surgeons and hospitals) decline with increasing volume (Khoury et al., 2019; McNeely et al., 2017). Thus, we assessed validity of the measure by examining the relationship between volume and the measure score for hospitals. To establish validity, we expect scores to be correlated with case volume at the hospital level.

We examined the relationship of performance of the CABG readmission measure scores (RSRRs) 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 CABG readmission measure scores would have a small association with the overall hospital Star Rating scores, with lower RSRRs associated with better Star ratings. With CABG surgical volume, we assume that lower RSRRs will be moderately associated with higher volume hospitals.

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

In addition, during measure development we established the face validity of the measure. To systematically assess face validity, we surveyed the Technical Expert Panel (TEP) and asked each member to rate the following statement using a six-point scale (1=Strongly Disagree, 2=Moderately Disagree, 3=Somewhat Disagree, 4=Somewhat Agree, 5= Moderately Agree, and 6=Strongly Agree): "The readmission rates obtained from the readmission measure as specified will provide an accurate reflection of quality."

Medical Records-based Validation

In collaboration with the Society of Thoracic Surgeons (STS), we performed a validation study of this measure using the national STS Adult Cardiac Surgery Database, including the following:

Validation of the administrative isolated CABG cohort

Validation of the administrative isolated CABG cohort consisted of matching, using probabilistic matching at the patient and hospital level, the administrative CABG cohort for the administrative readmission measure detailed in this application to the measure cohort for the proposed STS registry data-based CABG readmission measure. Non-matching patients were identified as either claims only patients (i.e., the administrative cohort defined them as isolated CABG patients while the STS registry did not) or registry only patients (i.e., the administrative cohort defined them as non-isolated CABG patients while the registry defined them as isolated CABG patients. This information was then used to further harmonize the administrative readmission cohort inclusion/exclusion criteria and codes to align as much as possible with the registry definition of isolated CABG procedures.

Validation of the administrative risk adjustment model

Validation of the administrative risk-adjustment model consisted of comparing the hospital-level RSRRs and performance category assigned by the administrative CABG readmission measure detailed in this application in the matched cohort of CABG patients to the RSRRs calculated and performance category assigned by the STS clinical data-based CABG readmission measure (also in the matched cohort and using identical methods for defining the outcome and performance categorization). For each of the two measures, RSRRs were estimated in a hierarchical logistic regression model with hospital-specific random intercept parameters. Methods of estimation were identical to the currently publicly reported CMS mortality and readmission measures for Acute Myocardial Infarction, Heart Failure and Pneumonia. A bootstrapping algorithm was used to construct a 95% interval estimate for each RSRR. To complete this analysis, we categorized hospitals into three performance groups -- "Better", "Same" and "Worse" than the national rate -- according to the methodology used for the currently publicly reported CMS mortality and readmission three performance groups -- "Better", "forme" and "Worse" than the national rate -- according to the methodology used for the currently publicly reported CMS mortality and readmission measures. We classified a hospital as performing "Better than the national rate" if the 95% interval estimate for that hospital was entirely below the

overall aggregate readmission rate for all hospitals, "Worse than the national rate" if the estimate for that hospital was entirely above the overall aggregate readmission rate, and "Same as the national rate" if the estimate included the overall aggregate readmission rate.

Statement of Intent and Process of Conversion

This application includes ICD-10 codes that correspond to the ICD-9 codes included in our measure specifications. The goal of conversion to ICD-10 was to convert this measure to a new code set, fully consistent with the intent of the original measure. ICD-10 codes were initially identified using 2016 general equivalence mapping (GEM) 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 currently in use for this measure. We examined this ICD-10 code set in a 6-month sample of ICD-10-coded claims submitted by hospitals after October 1,2016. The ICD-10-based specifications are attached in field the Data Dictionary.

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

TEP Face Validity

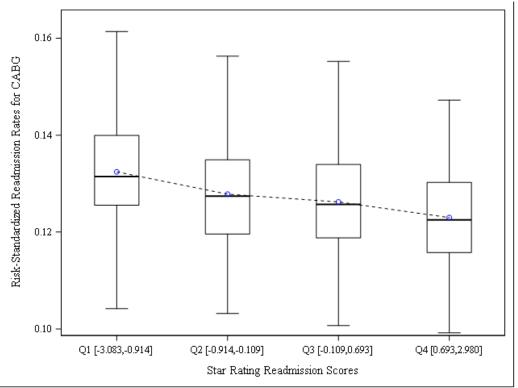
As mentioned above, during measure development we established the face validity of the measure through a systematic survey of the Technical Expert Panel (TEP). Each member was asked to rate the following statement using a six-point scale (1=Strongly Disagree, 2=Moderately Disagree, 3=Somewhat Disagree,

4=Somewhat Agree, 5= Moderately Agree, and 6=Strongly Agree): "The readmission rates obtained from the readmission measure as specified will provide an accurate reflection of quality."

Fourteen TEP members responded to the survey question as follows: Moderately Disagreed (2), Somewhat Disagreed (2), Somewhat Agreed (4), Moderately Agreed (5), and Strongly Agreed (1). Hence, 71% of TEP members agreed (somewhat, moderately, or strongly) that the measure will provide an accurate reflection of quality.

Correlation between CABG RSRRs and Star-Rating Readmission Group Scores

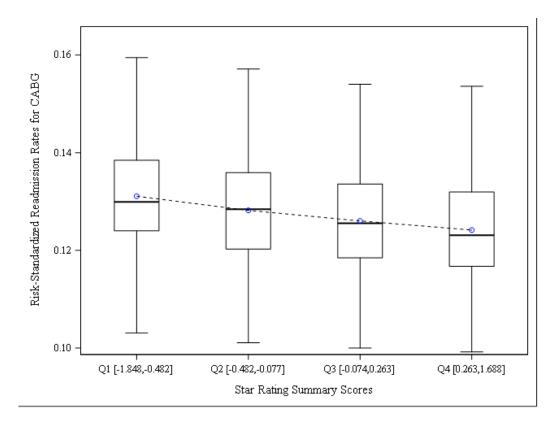
Figure 1 shows the box-whisker plots of the CABG readmission measure RSRRs within each quartile of Star-Rating readmission scores. The blue circles represent the mean RSRRs of Star-Rating readmission score quartiles. The correlation between CABG RSRRs and Star-Rating readmissions score is -0.307, which suggests that hospitals with lower CABG RSRRs are more likely to have higher Star-Rating readmission scores. Figure 1. Box-whisker plots of the CABG readmission measure RSRRs within each quartile of Star Rating readmission scores



Correlation between CABG RSRRs and Overall Star-Rating Scores

Figure 2 shows the Box-whisker plots of the CABG 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 CABG RSRRs and Star-Rating summary score is -0.238, which suggests that hospitals with lower CABG RSRRs are more likely to have higher Star-Rating summary scores.

Figure 2 – Box-whisker plots of the CABG readmission measure RSRRs within each quartile of Star-Rating summary scores



Correlation between CABG RSRRs and Hospital CABG Admission Volume

Table 3 shows the relationship between CABG RSRRs and hospital CABG admission volume among hospitals with more than 25 CABG admissions. Results show that mean RSRRs are slightly lower among high volume hospitals compared to lower volume hospitals.

Correlation coefficient between CABG admission volumes and RSRRs: Deciles of volume	(Total number of hospitals with more than 25 admissions=992) -0.13491 <.0001: # of Hospitals	(Total number of hospitals with more than 25 admissions=992) -0.13491 <.0001: Volume Range (# of admissions)	(Total number of hospitals with more than 25 admissions=992) -0.13491 <.0001: Mean RSRR
0%~10%	98	25-37	12.89
10%~20%	104	38-49	12.87
20%~30%	94	50-64	13.07
30%~40%	100	65-80	12.98
40%~50%	99	81-102	12.72
50%~60%	98	103-122	12.65
60%~70%	103	123-149	12.67
70%~80%	98	150-189	12.67
80%~90%	99	190-265	12.62

Table 3. Association between CABG RSRRs and Hospital CABG Admission Volume

Correlation coefficient between CABG admission volumes and RSRRs: Deciles of volume	(Total number of hospitals with more than 25 admissions=992) -0.13491 <.0001: # of Hospitals	(Total number of hospitals with more than 25 admissions=992) -0.13491 <.0001: Volume Range (# of admissions)	(Total number of hospitals with more than 25 admissions=992) -0.13491 <.0001: Mean RSRR
90%~100%	99	268-838	12.27

Medical-Records-Based Validation Results

As described above, using STS CABG registry data and in collaboration with STS, we performed a clinical data validation study of the administrative cohort definition, risk adjustment model and hospital performance assessment that are outlined in detail in the <u>original methodology report</u>. The risk-adjustment validation produced a substantial correlation of RSRRs between the two measures in a matched cohort of patients, with an intraclass correlation coefficient of 0.92. When hospitals were categorized as "Better", "Worse" or "No different" than the national rate, over 97% (807 of 829) of hospitals in the matched cohort were categorized identically by the two measures (the vast majority were considered "No different than the national rate" by either measure).

2b1.4. What is your interpretation of the results in terms of demonstrating validity? (i.e., what do the results mean and what are the norms for the test conducted?)

Empirical Validity Testing

This validation approach compares the 30-day CABG readmission measure results against the Star Rating readmission domain and summary scores. Figures 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 the Star Ratings readmission domain and summary scores and the CABG readmission measure indicate moderate associations, which is to be expected given that all measures are calculated through complex statistical models. Therefore, the results above show that the trend and results of the CABG readmission measure are in agreement with other measures of quality. Additionally, this validation approach compared various categories and deciles of hospital CABG admission volume with CABG readmission measure scores in Table 3 – these results demonstrate an observed trend of higher hospital volume with lower readmission rates, especially in hospitals with the largest volumes.

2b2. EXCLUSIONS ANALYSIS

NA \Box no exclusions – *skip to section* <u>2b4</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** below is the distribution of exclusions among hospitals with 25 or more admissions (Table 4):

	Exclusion	Ν	%	Distribution across hospitals (N=994: Min, 25 th , 50 th , 75 th percentile, max
1.	Discharged against medical advice (AMA)	45	0.03	(0.00, 0.00, 0.00, 0.00, 3.70)
2.	Without at least 30 days post-discharge enrollment in FFS Medicare for index admission	569	0.43	(0.00, 0.00, 0.00, 0.70, 5.41)
3.	Subsequent hospital stays for patients with additional CABG procedure admissions	61	0.05	(0.00, 0.00, 0.00, 0.00, 3.45)

Table 4. Distribution of Exclusions

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 0.03% 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 0.43% 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.

Exclusion 3 (Patients with subsequent admissions for CABG) accounts for 0.05% of all index admissions excluded from the initial index cohort. CABG procedures are expected to last for several years without the need for revision or repeat revascularization. A repeat CABG procedure during the measurement period likely represents a complication of the original CABG procedure and is a clinically more complex and higher risk surgery. Therefore, we select the first CABG surgery admission for inclusion in the measure and exclude subsequent CABG surgery admissions from the 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 <u>2b5</u>.

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

- □ No risk adjustment or stratification
- Statistical risk model with 26 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 a parsimonious model 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 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 and 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 mortality (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 CABG. 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 14)
- 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 26 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 social risk factors 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, Chang et al 2007; Gopaldas et al., 2009; Kim et al., 2007; LaPar et al., 2010; 2012; Lindenauer et al., 2013; Trivedi et al., 2014; Buntin et al., 2017; Hamadi et al., 2019; Anderson et al., 2016; Anderson et al., 2016). 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 American Community Survey 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 can be 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:

- ⊠ Published literature
- 🔀 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 5. Adjusted OR and 95% CIs for the CABG Readmission Hierarchical Logistic Regression Model OverDifferent 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% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
Age minus 65 (years above 65, continuous)	1.02	1.02	1.03	1.03
	(1.02-1.03)	(1.02-1.03)	(1.03-1.04)	(1.02-1.03)
Male	0.75	0.78	0.77	0.77
	(0.71-0.80)	(0.74-0.83)	(0.72-0.82)	(0.74-0.80)
Cardiogenic shock	1.25	1.28	1.22	1.25
	(1.05-1.49)	(1.08-1.52)	(1.02-1.46)	(1.13-1.39)
History of coronary artery bypass graft	1.16	1.06	1.13	1.12
(CABG) or valve surgery	(1.05-1.29)	(0.95-1.18)	(1.02-1.26)	(1.05-1.19)
Cancer; metastatic cancer and acute	1.00	0.97	1.07	1.01
leukemia (CC 8-14)	(0.93-1.07)	(0.90-1.04)	(0.99-1.15)	(0.97-1.06)
Diabetes mellitus (DM) or DM complications (CC 17-19, 122-123)	1.10	1.19	1.14	1.14
	(1.03-1.16)	(1.12-1.26)	(1.07-1.21)	(1.10-1.18)
Protein-calorie malnutrition (CC 21)	1.36	1.27	1.44	1.36
	(1.21-1.54)	(1.12-1.43)	(1.26-1.63)	(1.26-1.46)
Morbid obesity; other endocrine/metabolic/nutritional disorders (CC 22, 25-26)	0.99 (0.87-1.12)	0.85 (0.74-0.96)	0.89 (0.77-1.02)	0.91 (0.85-0.98)
Other significant endocrine and metabolic disorders; disorders of fluid/electrolyte/acid-base balance (CC 23- 24)	1.15 (1.06-1.24)	1.16 (1.08-1.26)	1.10 (1.02-1.19)	1.14 (1.09-1.19)
Severe hematological disorders (CC 46)	1.31	1.73	1.48	1.49
	(0.94-1.81)	(1.26-2.37)	(1.05-2.08)	(1.23-1.80)
Dementia or other specified brain disorders (CC 51-53)	1.27	1.27	1.23	1.25
	(1.14-1.42)	(1.14-1.42)	(1.10-1.38)	(1.18-1.34)
Major psychiatric disorders (CC 57-59)	1.33	1.22	1.18	1.24
	(1.17-1.51)	(1.07-1.39)	(1.04-1.35)	(1.15-1.34)
Hemiplegia, paraplegia, paralysis, functional disability (CC 70-74, 103-104, 189-190)	1.10 (0.95-1.27)	0.98 (0.84-1.14)	1.26 (1.09-1.46)	1.10 (1.01-1.20)
Polyneuropathy; other neuropathies (CC 75, 81)	1.13	1.13	0.99	1.09
	(1.05-1.22)	(1.05-1.22)	(0.92-1.07)	(1.05-1.14)
Congestive heart failure (CC 85)	1.19	1.27	1.29	1.25
	(1.10-1.27)	(1.19-1.37)	(1.19-1.38)	(1.20-1.30)
Specified arrhythmias and other heart rhythm disorders (CC 96-97)	1.10	1.08	1.10	1.10
	(1.03-1.17)	(1.01-1.15)	(1.03-1.17)	(1.06-1.14)
Stroke (CC 99-100)	1.02	1.10	1.10	1.07
	(0.89-1.17)	(0.96-1.26)	(0.96-1.27)	(0.99-1.16)
Cerebrovascular disease (CC 101-102, 105)	0.93	0.92	0.90	0.92
	(0.87-1.00)	(0.86-0.99)	(0.84-0.97)	(0.89-0.96)
Vascular or circulatory disease (CC 106-	1.14	1.09	1.04	1.09
109)	(1.07-1.21)	(1.02-1.16)	(0.97-1.11)	(1.05-1.13)

Variable	07/2016-	07/2017-	07/2018-	07/2016-
	06/2017	06/2018	06/2019	06/2019
	OR (95% CI)	OR (95% Cl)	OR (95% CI)	OR (95% CI)
Chronic obstructive pulmonary disease	1.41	1.38	1.41	1.40
(COPD) (CC 111)	(1.32-1.50)	(1.30-1.47)	(1.32-1.51)	(1.34-1.45)
Fibrosis of lung or other chronic lung disorders (CC 112)	0.97	1.17	1.15	1.09
	(0.84-1.12)	(1.02-1.33)	(1.01-1.32)	(1.01-1.18)
Pneumonia (CC 114-116)	1.18	1.31	1.16	1.21
	(1.09-1.28)	(1.21-1.42)	(1.06-1.27)	(1.16-1.27)
Other respiratory disorders (CC 118)	1.08	1.12	1.09	1.10
	(1.02-1.15)	(1.05-1.19)	(1.02-1.15)	(1.06-1.14)
Dialysis status (CC 134)	1.56	1.44	1.44	1.47
	(1.33-1.83)	(1.22-1.69)	(1.21-1.70)	(1.34-1.62)
Renal failure (CC 135-140)	1.36	1.37	1.32	1.35
	(1.27-1.45)	(1.28-1.46)	(1.23-1.40)	(1.30-1.40)
Decubitus ulcer or chronic skin ulcer (CC 157-161)	1.42	1.22	1.34	1.32
	(1.24-1.62)	(1.06-1.40)	(1.16-1.55)	(1.22-1.43)

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 prior endorsement maintenance forms for comparison purposes.

SRFs	2020 Prevalence % (IQR)	2016 Prevalence % (IQR)
Dual	4.70% (2.30-8.60%)	7.1% (4.4-11.0%)
AHRQ Low SES	14.6% (7.70-26.3%)	18.5% (7.5-3 <mark>7.2</mark> %)

The prevalence of social risk factors in the CABG cohort varies widely across measured entities in 2020. The median percentage of dual eligible patients was 4.70% (IQR 2.30%-8.60%) and the median percentage of patients with an AHRQ SES index score adjusted for cost of living at the census block group level equal to or below 42.7 (lowest quartile) was 14.6% (IQR 7.70%-26.3%) in 2020. These results are consistent with although lower than the 2016 results presented above.

SRFs	2020 Observed Rate	2016 Observed Rate
Dual (vs. Non-Dual)	19.2% (vs. 12.3%)	19.5% (vs. 14.5%)
AHRQ Low SES (vs. SES score above 42.7)	14.8% (vs 12.3%)	16.1% (vs. 14.6%)

The patient-level observed CABG readmission rates are higher for dual-eligible patients (19.2%) compared with 12.3% for non-dual patients in 2020. Similarly, the readmission rate for patients with an AHRQ SES index score equal to or below 42.7 (lowest quartile) was 14.8% compared with 12.3% for patients with an AHRQ SES index score above 42.7 in 2020. For both SRF variables, patient-level readmission rates have declined 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 moderate. In 2020, dual eligibility and the AHRQ SES index have effect sizes (odds ratios) of 1.32 and 1.13 when added independently to the model, Furthermore, the effect size of each variable is attenuated (1.29 and 1.10 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 8).

CABG 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 CABG readmission measure	0.64	0.62
Base Model plus AHRQ Low SES based on beneficiary residential 9-digit ZIP codes (SES9) as a social risk variable	0.64	0.62
Base Model plus dual eligibility (dual) as a social risk variable	0.64	0.62
Base Model plus SES9 and dual as social risk variables	0.64	

Table 8

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 0.037% (interquartile range [IQR] -0.023% - 0.047%) 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 0.139% (IQR -0.117% - 0.153%) with a correlation coefficient between RSRRs for each hospital of 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 0.981.

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 AHRQSES Index effects were significantly associated with CABG readmission in the decomposition analysis. That the hospital level effects were significant indicates that if the dual eligible or low AHRQSES 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 heart failure, COPD, and dialysis status (Figures 3 and 4; predicted probabilities for clinical variables). The clinical variables had the opposite pattern, with a greater effect at the patient level than at the hospital level for heart failure, COPD, and dialysis status. In sum, including SRF variables 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 SES.

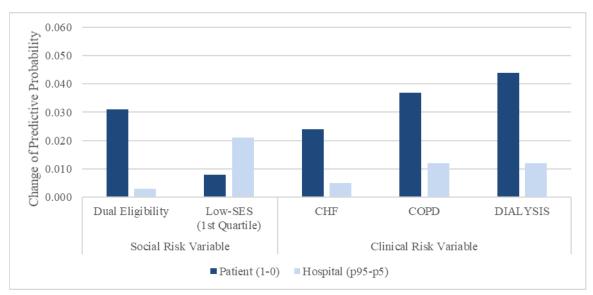
Second, the predominance of the hospital-level effect of SRFs in the decomposition analyses for 2020 and 2016 (Figures 3 and 4 below) suggests the risk associated with low SES is in large part due to lower quality of care at hospitals where more patients with these risk factors are treated. Direct adjustment 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 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 9. Parameter Estimates for Hospital-Level and Patient-Level in 2020 and 2016 from Decomposition

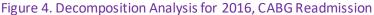
Parameter	2020 Estimate (standard error), p-value	2016 Estimate (standard error), p-value
Low SES census block group (AHRQ SES index linked to 9-digit ZIP – Adjusted for Cost of Living) – Patient Level	0.070 (0.002), <0.01	0.036 (0.020), 0.078
Low SES census block group (AHRQ SES index linked to 9-digit ZIP – Adjusted for Cost of Living) – Hospital Level	0.573 (0.088), <0.0001	0.219 (0.051), <0.0001
Dual-Eligible – Patient Level	0.269 (0.033), <0.0001	0.171 (0.027), <0.0001
Dual-Eligible – Hospital Level	0.437 (0.129), <0.001	0.340 (0.147), <0.05

Analysis

Figure 3. Decomposition Analysis for 2020, CABG Readmission



0.060 Change of Predictive Probability 0.050 0.040 0.030 0.020 0.010 0.000 Dual Eligibility Low-SES CHF COPD DIALYSIS (1st Quartile) Social Risk Variable Clinical Risk Variable ■ Patient (1-0) ■ Hospital (p95-p5)



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. Peer-reviewed literature supports this claim (Anderson et al., 2016).

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:

Anderson JE, Li Z, Romano PS, Parker J, Chang DC. Should Risk Adjustment for Surgical Outcomes Reporting Include Sociodemographic Status? A Study of Coronary Artery Bypass Grafting in California. *J Am Coll Surg.* 2016;223(2):221-230. doi:10.1016/j.jamcollsurg.2016.05.008.

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;

<u>http://www.qualityforum.org/Publications/2014/08/Risk_Adjustment_for_Socioeconomic_Status_or_Other_S</u> 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)

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.

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

If stratified, skip to 2b3.9

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

Development and Validation Dataset:

2009 development cohort:

C-statistic = 0.62

Predictive ability (lowest decile %, highest decile %): (8.7, 29.8)

2008 validation cohort:

C-statistic = 0.63

Predictive ability (lowest decile %, highest decile %): (8.8, 30.5)

2010 validation cohort:

C-statistic = 0.63

Predictive ability (lowest decile %, highest decile %): (8.4, 30.3)

Results for the Testing Dataset:

C-statistic = 0.64

Predictive ability (lowest decile %, highest decile %): (6.2, 25.7)

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

2009 development cohort: Calibration (over-fitting statistics): (0, 1)

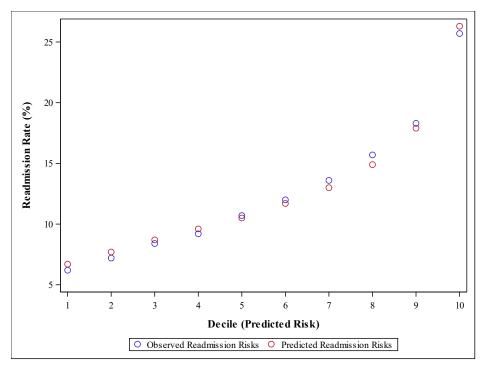
2008 validation cohort: Calibration (over-fitting statistics): (0.02, 1.01)

2010 validation cohort: Calibration (over-fitting statistics): (-0.03, 1.00)

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

The risk decile plot (Figure 5) 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 testing dataset 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** indicates 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 readmission 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. 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 CABG 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.

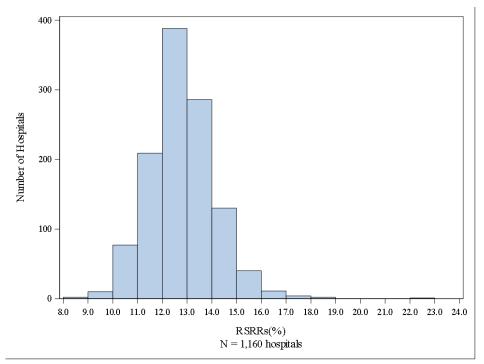
References:

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 CABG RSRRs among hospitals.

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



Out of 1,160 hospitals in the measure cohort, 6 performed "better than the U.S. national rate," 972 performed "no different from the U.S. national rate," and 14 performed "worse than the U.S. national rate." 168 were classified as "number of cases too small" (fewer than 25) to reliably tell how well the hospital is performing. The range of RSRRs in the testing dataset was 8.6% - 22.6%, demonstrating considerable variation in readmission rates.

The median odds ratio was 1.23.

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 CABG at a higher risk hospital compared to a lower risk hospital. A value of **1.23** indicates that a patient has a **23%** 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 is substantial.

The variation in rates and number of performance outliers suggests there remain differences in the quality of care received across hospitals performing CABG procedures on Medicare FFS patients. This evidence supports continued measurement to reduce the variation.

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 CABG readmission measure used claims-based data for development and testing. There were 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).

N/A

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?
	Payment Program
	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.Sterritories 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) and critical access hospitals (1,160) were included in measure calculation. Only those hospitals performing at least 25 qualifying isolated CABG procedures 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 the summer 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 allows 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 analyses (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.

Questions and Answers (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 three 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 CABG 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. Queries about how cohorts and outcomes are defined;
- 8. Queries about how to calculate the measure and to interpret the statistical model including the interpretation of coefficients for risk variables;
- 9. Requests for hospital-specific measure information, such as data included in the HSRs;
- 10. Questions on how readmissions are capture for patients admitted for an AMI and have a CABG procedure during the index admission; and
- 11. Questions about technical specifications of the measure as it pertains to the payment programs.

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

Summary of Question and Comments from Other Stakeholders:

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

- 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 risk-adjustment 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. Questions about how transfers are handled in the measure calculation; and
- 6. Requests for clarification on measure national rates.

Queries about the implementation of the measure in CMS initiatives and payment programs; and

7. Requests about hospital-specific measure information including mock Hospital-Specific Reports.

Summary of Relevant Publications from the Literature Review:

Since the last endorsement cycle, we have reviewed more than 300 articles related to readmissions following isolated CABG surgery. Relevant articles shared key themes related to: considerations for additional risk adjustment variables, including social risk factors and other clinical comorbidities; exploration of potential association between hospital surgical volume and CABG readmissions; reasons for readmission; and trends in patient characteristics and readmission rates over the last two decades.

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 CABG readmission measure for the 3-year period between July 1, 2016 and June 30, 2019 was 12.7%. The median RSRR decreased by 0.6 absolute percentage points from July 2016-June 2017 (median RSRR: 12.9%) to July 2018-June 2019 (median: RSRR: 12.3%).

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)

0114 : Risk-Adjusted Postoperative Renal Failure

0115 : Risk-Adjusted Surgical Re-exploration

0119 : Risk-Adjusted Operative Mortality for CABG

- 0129 : Risk-Adjusted Postoperative Prolonged Intubation (Ventilation)
- 0130 : Risk-Adjusted Deep Sternal Wound Infection
- 0131 : Risk-Adjusted Stroke/Cerebrovascular Accident

0330 : Hospital 30-day, all-cause, risk-standardized readmission rate (RSRR) following heart failure (HF) hospitalization

0505 : Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following acute myocardial infarction (AMI) hospitalization.

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

2558 : Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following coronary artery bypass graft (CABG) surgery

3494 : Hospital 90-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Coronary Artery Bypass Graft (CABG) Surgery

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.

The CABG readmission measure, which was developed in close collaboration with STS, has a target population (i.e., isolated CABG patients) that is harmonized with the above measures to the extent possible given the differences between clinical and administrative data. The exclusions are nearly identical to the STS measures' cohort exclusions with the exception of epicardial MAZE procedures; STS excludes these procedures from the registry-based CABG readmission measure cohort because the version of registry data used for measure development did not allow them to differentiate them from open maze procedures. The age range for the proposed CABG readmission and existing NQF-endorsed STS measure cohorts differs; STS measures are specified for age 18 and over, and the CABG readmission measure is currently specified for age 65 and over. The proposed CABG readmission measure is harmonized with the above measures to the extent possible given the different data sources used for development and reporting.

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.)

This measure was developed concurrently with a clinical registry data-based readmission measure (Riskadjusted readmission measure for coronary artery bypass graft (CABG)). The measure steward for the registrybased readmission measure for CABG is also CMS; STS developed the measure. Effort was taken to harmonize both the registry-based and administrative-based measures to the extent possible given the differences in data sources.

CMS developed these two "competing" measures at the same time to allow for maximum flexibility in implementation for quality improvement programs across different care settings. The STS cardiac surgery registry currently enrolls most, but not all, patients receiving CABG surgeries in the U.S. The proposed CABG readmission measure will capture all qualifying Medicare FFS patients undergoing CABG regardless of whether their hospital or surgeon participates in the STS registry.

This claims-based CABG readmission measure was developed with the goal of producing a measure with the highest scientific rigor and broadest applicability. The measure is harmonized with the above existing and proposed measures to the extent possible given the different data sources used for development and reporting.

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, doris.peter@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.

Technical Expert Panel Members:

Joseph V. Agostini, MD, Aetna

Tanya Alteras, MPP, National Partnership for Women and Families

Mary Barton, MD, MPP, National Committee for Quality Assurance (NCQA)

Carol Beehler, RN, NEA-BC, Pricewaterhouse Coopers

Todd Michael Dewey, MD, Southwest Cardiothoracic Surgeons

Lee Fleisher, MD (Served from March 30, 2012 to May 25, 2012), American Society of Anesthesiologists, University of Pennsylvania School of Medicine

Paul Kurlansky, MD, Florida Heart Research Institute, Inc

Frederic Masoudi, MD, MSPN, University of Colorado-Denver, Senior Medical Office of National CV Data Registries

Christine McCarty, MD, Cardiovascular Surgical Institute

Joseph Parker, PhD, State of California: Office of Statewide Health Planning and Development,

Kenneth Sands, MD, MPH, Beth Israel Deaconess Medical Center

Ed Savage, MD, Cleveland Clinical Florida

Stephen Schmaltz, PhD, The Joint Commission

Richard Shemin, MD, UCLA Medical Center

Alan Speir, MD, Inova Fairfax Hospital

Working Group Panel Members:

Arnar Geirsson, MD, Yale School of Medicine

David Shahian, MD, STS Workforce on National Databases, Harvard Medical School, Massachusetts General Hospital

Measure Developer/Steward Updates and Ongoing Maintenance

Ad.2 Year the measure was first released: 2015

Ad.3 Month and Year of most recent revision: 09, 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