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MAP Hospital Preliminary Analyses Worksheet

MUC20-0003 Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (Hospital IQR Program)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0004 Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) (Hospital OQR Program)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0005 Breast Screening Recall Rates (Hospital OQR Program)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0032 Global Malnutrition Composite Score (Hospital IQR Program)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0032 Global Malnutrition Composite Score (Medicare and Medicaid Promoting Interoperability Programs)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0039 Standardized Hospitalization Ratio for Dialysis Facilities (SHR) (ESRD QIP)

- Measure Specifications
- Preliminary Analysis

- Public Comment

MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (ASCQR)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (ESRD QIP)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (Hospital OQR Program)

- Measure Specifications
- Preliminary Analysis
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MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (Hospital IQR Program)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (IPFQR)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (PCHQR)

- Measure Specifications
- Preliminary Analysis
- Public Comment

MUC20-0048 SARS-CoV-2 Vaccination Coverage for Patients in End-Stage Renal Disease (ESRD) Facilities (ESRD QIP)

- Measure Specifications

- Preliminary Analysis
- Public Comment

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0003
Other Measure Identification Numbers	N/A
Title	Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)
Program	Hospital Inpatient Quality Reporting Program
Workgroup	MAP Hospital
In what state of development is the measure?	Fully Developed
State of Development Details	This PRO-PM was tested on eligible procedures performed between July 1, 2016 and June 30, 2017 for which complete PRO data from both the preoperative and postoperative assessment were submitted. For reliability and validity testing, all CJR participant hospitals with at least 25 THA/TKA patients with complete PRO data in the measurement period were included (n=123). For response bias analysis, all eligible procedures at all 238 CJR participant hospitals were included. (A case-volume cut-off of 25 was selected as it provided high measure result reliability and was consistent with volume thresholds used for public reporting of claims-based measures with which this measure was intentionally harmonized; we therefore recommend this measure be reported using a minimum case-volume cut-off of 25 or greater.) (Complete PRO and risk variable data was defined as the submission of preoperative PRO and risk variable data with no missing or out-of-range values for required data elements and that could be matched to postoperative PRO data with no missing or out-of-range values, for an elective primary THA/TKA procedure identified in claims data for the measurement period.) Reliability and Validity of PROM instruments: The reliability results from the literature demonstrate that the HOOS, JR and the KOOS, JR PROM instruments are sufficiently reliable and exceed accepted norms for reliability testing. The results assessing internal consistency indicated PSI values of 0.86 - 0.87 for the HOOS, JR1 and 0.84-0.85 for the KOOS, JR2. Values above 0.7 indicate the ability of the instruments to differentiate patients with varying levels of pain and functioning, which in turn provides evidence of good internal consistency. Test-retest reliability results for the HOOS domains from which HOOS, JR questions were drawn (Pain and Activity of Daily Living domains) revealed high intra-class correlation coefficients (ICCs), ranging from 0.75 to 0.97. Likewise, test-retest reliability for the KOOS domains from which the KOOS, JR questions were drawn (ICCs of 0.75 - 0.93) provided evidence of good reliability. The validity results from the literature demonstrate that the HOOS, JR and the KOOS, JR PROM instruments are valid and meaningful measures for assessing PROs following THA/TKA procedures. The HOOS, JR and the KOOS, JR showed very high responsiveness, well beyond the 0.8 standardized response mean value considered “very large” 31. Spearman correlation values between the HOOS, JR and the HOOS domains from which the HOOS, JR questions were drawn (Pain and Activity of Daily Living domains) were high; likewise, Spearman correlation values between the KOOS, JR and the KOOS Pain and Activity of Daily Living domains were high, and were moderate between the KOOS, JR and the Symptom domain. Floor effects were small; ceiling effects for the HOOS, JR were 37%–46%, but were comparable to or better than HOOS domains and the WOMAC1,2. Measure Score Reliability and Validity: Measure score reliability was tested using signal-to-noise analysis to describe how well the measure can distinguish performance of one hospital from another 30,32. The signal is the proportion of the variability in measured performance that can be explained by real differences in performance. 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. The signal-to-noise

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	reliability results indicate a median of 0.96 and a mean of 0.95 (0.263). The interquartile range was 0.0366 (0.9351 [Q1] to 0.9717 [Q3]). This indicates excellent reliability. To assess empirical measure score validity, we compared the THA/TKA PRO-PM risk-standardized improvement rates (RSIRs) to the NQF endorsed Hip/Knee Complication Measure (NQF #1550: Hospital-level risk-standardized complication rate (RSCR) following elective primary THA/TKA.) The THA/TKA Complications measure estimates the risk-adjusted rate that patients who have experienced an elective primary THA/TKA experience at least one of eight complications within 90 days of the procedure. The RSCR is categorized into 3 groups: worse than national average, same as national average, and better than national average. Data for the hospital RSCRs from April 1, 2015 to March 31, 2018 were compared to RSIRs for procedures performed July 1, 2016 to June 30, 2017. We examined the distribution of THA/TKA PRO-PM RSIRs by THA/TKA RSCR national categories within hospitals submitting complete PRO data for at least 25 THA/TKA procedures: Hospitals worse than national average (those with higher complication rates); Hospitals the same as national average; and Hospitals better than national average (those with lower complication rates). Comparison of THA/TKA PRO-PM RSIRs to RSCR categories indicated an increasing monotonic trend. Those hospitals in the “RSCR Worse than National Average” category had lower median RSIRs (51.87%) than the median RSIR (66.49%) of hospitals in the "RSCR Same as National Average" category, which is lower than that of hospitals in the "RSCR Better than National Average" category (71.13%). The hospitals with lower risk-adjusted complication rates had higher risk-adjusted THA/TKA improvement rates. As these outcomes are not clinically expected to be perfectly correlated but do reflect hospital-level care and processes impacting quality of care for patients experiencing elective primary THA/TKA surgery, we interpret the increasing monotonic trend between RSIRs and RSCR national categories as reflective of empiric measure validity. Response Bias Analysis: Potential response bias due to non-response of PROs was addressed using stabilized inverse probability weighting, created with a multinomial logistic regression to calculate stabilized inverse probability weights. Due to the voluntary nature of PRO survey data and because PRO data are unlikely to be missing at random, we understand that accounting for potential non-response bias is important for this measure. All eligible THA/TKA procedures performed during the measurement period at the 238 hospitals submitting complete PRO and risk variable data for at least one of these procedures were identified via CMS claims data. These were categorized into one of three PRO response groups (complete PRO submission, incomplete PRO submission and no response). Variables associated with unit non-response were identified in the data and through a literature review. Propensity scores were calculated using a multinomial logistic regression where the outcome was 1) complete PRO submission, 2) incomplete PRO submission, and 3) no response. Stabilized Inverse Probability Weights (IPW) were calculated for each of the three groups and incorporated into the hierarchical risk-adjustment model for substantial clinical benefit improvement following elective primary THA/TKA and used in calculation of the risk-adjusted and bias-adjusted RSIRs. Incorporating the stabilized weights in the calculation of the RSIRs helps to reduce bias due to non-response by giving higher weight to patients who were less likely to respond and deflating the weight of patients who were more likely to respond based on patient characteristics. Weighting the responders based on their likelihood of response, given their patient characteristics, helps reduce non-response bias in our RSIR measure. The comparison of hospital RSIRs for risk-adjusted model of substantial clinical benefit improvement with stabilized inverse probability weighting and without stabilized inverse probability weighting revealed only a small impact on the measure results of adjusting for potential non-response. However, we expect that non-response bias will be a factor for the THA/TKA PRO-PM measure, due to associations with non-response including socioeconomic status and health status. We therefore retained response bias adjustment for the measure results. References 30. Adams J, Mehrota, A, Thoman J, McGlynn, E.

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	(2010). Physician cost profiling – reliability and risk of misclassification. NEJM, 362(11): 1014-1021. 31. Steiner DL, Norman GR. (2003). Health Measurement Scales: A Practical Guide to Their Development and Use. London, UK: Oxford University Press. 32. Yu H, Mehrota A, Adams J. (2013). Reliability of utilization measures for primary care physician profiling. Healthcare, 1:22-29.
Measure Description	The measure will estimate a hospital-level, risk-standardized improvement rate for PROs following elective primary THA/TKA for Medicare fee-for-service (FFS) patients 65 years of age or older. Substantial clinical benefit improvement will be measured by the change in score on the joint-specific patient-reported outcome measure (PROM) instruments, measuring hip or knee pain and functioning, from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 270 to 365 days following surgery).
Numerator	The numerator is the risk-adjusted proportion of patients undergoing an elective primary THA/TKA who meet or exceed a substantial clinical benefit threshold of improvement between preoperative and postoperative assessments on joint-specific PROM surveys as follows:-For THA patients, meeting or exceeding the substantial clinical benefit of a 22-point increase in score on the Hip dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR)1, and-For TKA patients, meeting or exceeding the substantial clinical benefit threshold of a 20-point increase in score on the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR)2. References 1. Lyman S, Lee YY, Franklin PD, Li W, Mayman DJ, Padgett DE. (2016a). Validation of the HOOS, JR: A Short-form Hip Replacement Survey. Clinical Orthopaedics and Related Research®, 474(6):1472-1482. 2. Lyman S, Lee YY, Franklin PD, Li W, Cross MB, Padgett DE. (2016b). Validation of the KOOS, JR: A Short-form Knee Arthroplasty Outcomes Survey. Clinical Orthopaedics and Related Research®, 474(6):1461-1471.
Denominator	The cohort (target population) includes Medicare FFS patients 65 years of age and older undergoing elective primary THA/TKA procedures.
Exclusions	Denominator exclusion: Patients with staged procedures, defined as two or more elective primary THA or TKA procedures performed on the same patient during distinct hospitalizations during the measurement period, are excluded from the measure. The overlapping recovery period for staged procedures occurring within one year of each other makes including them in a PRO-PM cohort difficult in two ways: 1) the recovery from one procedure may negatively impact recovery from the other procedure; and 2) it may be challenging to fully distinguish the recovery for either of the procedures from the other with postoperative PRO data. (collected 270 to 365 days after surgery). Therefore, at this time, the measure focuses on patients receiving unilateral or simultaneous bilateral (not staged) THA/TKA procedures.
Measure type	Patient Reported Outcome
What is the NQF status of the measure?	Endorsed
NQF ID number	3559
Year of next anticipated NQF CDP endorsement review	2020
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A

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Is the measure being submitted exactly as endorsed by NQF?	N/A
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	Survey (HOOS, JR/KOOS, JR, Mental Health Subscale of PROMIS Global and VR-12), PROMIS, Claims, Other data (EDB, MBSF, American Community Survey data)
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	Centers for Medicare and Medicaid Services (CMS) administrative data is used to identify eligible THA/TKA procedures for the measure cohort and for clinical comorbidities used in the risk adjustment model.
At what level of analysis was the measure tested?	Facility
In which setting was this measure tested?	Hospital Inpatient
What NQS priority applies to this measure?	
What one primary meaningful measure area applies to this measure?	Functional outcomes
What secondary meaningful measure area applies to this measure?	Management of chronic conditions
What one primary healthcare priority applies to this measure?	Strengthen person and family engagement as partners in their care
What secondary healthcare priority applies to this measure?	Promote effective prevention and treatment of chronic disease
What area of specialty best fits the measure?	Orthopedic Surgery
What is the target population of the measure?	The cohort for this measure is Medicare FFS patients 65 years of age and older undergoing an elective primary THA/TKA procedure at a non-federal short-term acute care hospital. Inclusion criteria are harmonized with CMS's existing measure cohort for the hospital-level 90-day risk-standardized complication measure, and include patients:

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	Enrolled in Medicare FFS Part A and Part B for the 12 months prior to the date of the index admission, and enrolled in Part A during the index admission; Discharged alive from a non-federal short-term acute care hospital; and Undergoing only elective primary THA/TKA procedures (patients with fractures and revisions not included).
Is this measure an eCQM?	No
If eCQM, enter Measure Authoring Tool (MAT) number	N/A
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	N/A
Comments	N/A
Measure steward	Centers for Medicare & Medicaid Services
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Poyer, James; (410) 786-2261; james.poyer@cms.hhs.gov
Primary Submitter Contact Information	Rachel Johnson-DeRycke; Yale New Haven Health Services Corporation/Center for Outcomes Research and Evaluation (YNHHSC/CORE); (203) 764-6760; rachel.johnson-derycke@yale.edu
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	None
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not	N/A

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recommended in those year(s)?	
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The primary data source for development and testing of this measure was patient-reported outcome data collected with PROM instruments and additional patient and provider-reported risk variable data collected through the Center for Medicare and Medicaid Innovation (CMMI) Comprehensive Care for Joint Replacement (CJR) payment model. This model is an ongoing proof of concept among participating hospitals for broad, prospective collection of PRO data, implementing real-world data collection and data submission for centralization, risk adjustment and measure calculation. Data from Medicare Parts A and B claims were used for identifying eligible elective primary THA/TKA procedures and for identifying comorbid conditions for risk adjustment. The Medicare Enrollment Database (EDB) was used to assess Medicare FFS enrollment and identify patient race, and the Master Beneficiary Summary File (MBSF) was used to determine dual eligibility status. The Agency for Healthcare Research and Quality (AHRQ) socioeconomic status (SES) index score was derived from American Community Survey data.
How is the measure expected to be reported to the program?	Other (Patient-Reported Outcomes-Based Performance Measure [PRO-PM])
Is this measure similar to and/or competing with	Yes

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measure(s) already in a program?	
Which existing measure(s) is your measure similar to and/or competing with?	NQF # 2653: Average change in functional status following total knee replacement surgery (Developed by MN Community Measurement for the MIPS Program)
How will this measure be distinguished from other similar and/or competing measures?	This PRO-PM measure differs from NQF #2653 in attribution, cohort, outcome, risk adjustment, and an approach to response bias. Attribution: This PRO-PM is a hospital-level quality measure, whereas NQF #2653 is a clinician-level measure. Cohort: This PRO-PM includes both THA and TKA procedures and includes only primary, not revision, procedures, based upon clinical input that revision procedures are more complicated to perform and patient-reported outcomes may be influenced by the initial surgery. The target population is Medicare FFS beneficiaries 65 years of age and older. NQF #2653 includes only TKA procedures, includes knee replacement revisions as well as primary procedures, and includes all adults 18 years of age and older. Outcome: This PRO-PM collects PROs with the HOOS, JR for THA patients and the KOOS, JR for TKA patients; these non-proprietary instruments were supported by both clinicians and patients. Timing of PRO data collection is 90 – 0 days prior to and 270 – 365 days following surgery. The numerator measures substantial clinical benefit improvement for each patient from preoperative to postoperative assessment with a binary outcome (Yes/No), and the measure produces a risk-standardized improvement rate (RSIR) that elucidates for hospitals the risk-adjusted proportion of patients with improvement and those without improvement. In contrast, NQF #2653 collects PRO data with the Oxford Knee Score three months prior to and 9 – 15 months following surgery, and measures average change in knee function score. The outcome definition of substantial clinical benefit, with a defined threshold for change in PROM score, allows patients with poorer baseline PRO scores more room to improve and thus a greater opportunity to achieve substantial clinical benefit. This was identified by our technical expert panel (TEP) members as a specific benefit of measuring substantial clinical benefit versus average change; measuring substantial clinical benefit incentivizes providers to offer and perform THA/TKA procedures even on patients with poor PRO scores. In addition, TEP and Patient Working Group concerns with measuring an average change score included the fact that hospitals with all average outcomes would look similar to hospitals whose patients either did very well or very poorly (bimodal distributed outcomes), thus providing potentially misleading information to consumers and patients. Risk Adjustment: The risk model for this PRO-PM includes important risk variables supported by the TEP and other expert clinical consultants including health literacy, other musculoskeletal pain and chronic narcotic use which are not included in NQF #2653; these risk variables were identified and tested based upon input from orthopedic professional societies, including AAHKS and AAOS, through public comment (Centers for Medicare & Medicaid Services, CJR Final Rule 2015, Section III.D.3.A).Non-Response Bias: The measure results for this PRO-PM have been weighted for potential bias due to non-response of PROs. Using stabilized inverse probability weighting. Due to the voluntary nature of PRO survey data and because PRO data are unlikely to be missing at random, we understand that accounting for potential non-response bias is important for this measure. There is no approach to addressing non-response bias for NQF #2653.
Rationale for how this measure will add to the CMS program	The benefits of this PRO-PM over NQF #2653 include the following: 1) This PRO-PM is attributed to hospitals rather than clinicians, and therefore provides a signal of hospital quality. 2) This PRO-PM reflects outcomes for both THA and TKA recipients (rather than TKA recipients only), allowing for measurement of a greater number of patients and hospitals to provide CMS with broader influence on quality improvement. This approach aligns with the typical provision of orthopedic care within hospitals, delivered to patients

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	undergoing THA/TKA procedures by the same providers and hospital staff. 3) This PRO-PM assesses improvement in patient-reported pain and function using a binary outcome that elucidates for hospitals and patients the risk-adjusted proportion of patients with and without improvement (a clear, understandable metric that patients support), and is preferable to measuring an average change score, as NQF #2653 does, which cannot distinguish between hospitals with mostly average outcomes from hospitals whose patients either did very well or very poorly. In addition, using a substantial clinical benefit to define the measure outcome ensures that the measure does not penalize clinicians who operate on those patients with the worst baseline pain and function (often those with higher social risk or non-white race). NQF Measure #2653 uses an average change score adjusted for the baseline PROM score – this fundamentally equates to measuring post-operative PROM scores, which would incentivize surgeons to operate on those with the least severe symptoms at baseline and potentially avoid patients with the most severe pain and functional limitations at baseline. This would likely result in worsening disparities over time. 4) This PRO-PM uses a more robust and stakeholder-driven risk model and methodology to address non-response bias, anticipated to produce a measure with greater face validity with stakeholders. Specifically, this measure includes key clinical risk variables for a PRO-PM identified by clinical experts and supported by orthopedic professional societies, such as health literacy, back pain and contralateral leg pain. These ensure accurate assessment of the index THA/TKA procedure and account for concomitant comorbidities such as chronic back or contralateral joint disease that can interfere with PROM interpretation. In addition, this measure accounts for non-response bias. We have seen no evidence of NQF #2653 analytically addressing non-response bias. Non-response bias is a critical potential threat to the validity of PRO-PMs and failure to account for it may lead to worsening disparities. 5) This PRO-PM is harmonized with related measures including NQF #1550 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and total knee arthroplasty (TKA) and Risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) Eligible Clinicians and Eligible Clinician Groups (MUC19-28).
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	In 123 hospitals with at least 25 THA/TKA patients with complete PRO data in the measurement period, we found variation in RSIRs suggesting meaningful differences in performance measure scores across hospitals. The mean risk-standardized improvement rate (representing the risk-standardized percentage of patients achieving substantial clinical benefit improvement) across hospitals was 60.16% with a standard deviation of 19.58. The minimum hospital RSIR was 6.65% and the maximum hospital RSIR was 86.84%. The interquartile range (54.36 – 72.51%) represents a difference of 18 percentage points, and the difference between the 10th and 90th percentiles (20.94% and 78.85%, respectively) is just shy of 58 percentage points. This variation indicates an important quality gap among hospitals measured. Variation in hospital performance was also evaluated by calculating the median odds ratio (OR) for all hospitals in the dataset (n=238). The median OR represents the median increase in odds of the patient outcome (substantial clinical benefit improvement in PROM score from preoperative to postoperative assessment) if a procedure on a single patient was performed by a higher performing hospital compared to a lower performing hospital. It is calculated by taking all possible

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	combinations of hospitals always comparing the higher performing hospitals to the lower performing hospitals. The median OR is interpreted as a traditional odds ratio would be. Results suggest significant and substantial increases in the likelihood of substantial clinical benefit improvement by higher performing hospitals compared to lower performing hospitals. At the hospital level, the median OR value indicates that a patient is 3.44 times more likely to achieve substantial clinical benefit improvement if their elective primary THA/TKA procedure was performed by a higher performing hospital than by a lower performing hospital.
Unintended consequences	N/A
Which clinical guideline(s)?	This measure aligns with federal promotion of patient-centered approaches to health care quality improvement and with orthopedic and medical society recommendations for PRO data collection for improved orthopedic care. The National Quality Strategy (NQS), led by the Agency for Healthcare Research and Quality, has identified patient centeredness as one of its six priorities for addressing a range of health care quality concerns6. Similarly, the National Academy of Medicine (previously known as the Institute of Medicine [IOM]) has identified patient-centeredness as one of its quality domains5. Both the American Academy of Orthopaedic Surgeons and the American College of Rheumatology have expressed support for the collection of PRO data in clinical practice to improve outcomes3,4. This measure would encourage more widespread use of PROs in clinical outcome measurement, and increase the focus on patient centeredness in improving healthcare quality. References 3. American Academy of Orthopaedic Surgeons. 2015. Patient Reported Outcome Measures. Retrieved June 2, 2020, from https://www5.aaos.org/CustomTemplates/landingPage.aspx?id=4294968282&ssopc=1. 4. Barber CEH, Zell J, Yazdany J, et al. 2019 American College of Rheumatology Recommended Patient-Reported Functional Status Assessment Measures in Rheumatoid Arthritis. Arthritis Care Res (Hoboken). 2019;71(12):1531-1539. doi:10.1002/acr.24040. 5. Committee on Quality Health Care in America, Institute of Medicine (IOM). Crossing the Quality Chasm: A New Health System for the 21st Century. Washington, D.C.: National Academy Press; 2001: http://books.nap.edu/openbook.php?record_id=10027&page=R1. Accessed 2013. 6. Priorities of the National Quality Strategy. Content last reviewed September 2018. Agency for Healthcare Research and Quality, Rockville, MD. https://www.ahrq.gov/research/findings/nhqrdr/nhqdr15/priorities.html.
Briefly describe the peer reviewed evidence justifying this measure	Elective primary THA/TKA procedures are well-suited for PRO measurement. Unlike procedures that are intended to promote survival, these procedures are specifically intended to improve function and reduce pain, outcomes best reported by patients, which makes PROs a meaningful outcome metric to assess for this population. THA/TKAs are important, effective procedures performed on a broad population, and the patient-reported outcomes for these procedures (for example, pain, mobility, and quality of life) can be measured in a scientifically sound way 7,8,9,12,15,16,18,19,23,24,25,27,29 and are influenced by a range of improvements across the full spectrum of care. THA/TKA provides a suitable environment for optimizing care, as there are many studies indicating how providers can improve outcomes of the patients by addressing aspects of pre-, peri-, and postoperative care 10,11,14,17,20,21,22,26. Optimal clinical outcomes depend not just on the surgeon performing the procedure, but also on: the entirety of the team's efforts in the care of the patient; care coordination across provider groups and specialties; and the patients' engagement in their recovery13,26. Even the best surgeon will not get outstanding results if there are gaps in the quality of care provided by others caring for the patient before, during, and/or after surgery. The goal of hospital-level outcome measurement is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. References 7. Alviar M, Olver J, Brand C, Hale T, Khan F. Do Patient-Reported Outcome Measures Used in Assessing Outcomes in Rehabilitation After Hip and Knee Arthroplasty

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Preliminary Analysis – MUC ID: MUC20-0003 Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA)

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This fully developed measure addresses the high priority Meaningful Measure Area of functional outcomes and strengthening person and family engagement as partners in their care. The Hospital IQR Program currently does not include measures of person and family engagement related to total hip or total knee arthroplasty (THA/TKA). However, the program does include a payment measure for hip and/or knee arthroplasty and a complication rate measure following hip and/or knee arthroplasty measures. These related measures capture the same target population but different areas of measure focus.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	Yes	The measure is an endorsed patient-reported outcome performance measure (PRO-PM) that passed the Spring 2020 NQF CDP and CSAC endorsement review. The developer cites several studies indicating how providers can improve outcomes of the patients by addressing aspects of pre-, peri-, and postoperative care. The developer further cites studies that suggest that optimal clinical outcomes may be influenced by the surgeon performing the procedure, the team's efforts in the care of the patient, care coordination across provider groups and specialties, and the patients' engagement in their own recovery (Feng et al., 2018; Saufl et al., 2007). During the most recent endorsement review several validity considerations were raised including attributing changes in joint function to the hospital (vs. care such as rehabilitation services) during the follow-up interval, the exclusion of staged procedures potentially eliminating up to 43% of procedures, and the basis of the 25-case volume exclusion threshold. While these validity considerations were raised, the measure was ultimately endorsed.
Does the measure address a quality challenge?	Yes	According to the measure developer, THA and TKA are commonly performed in older patients who have noticeable pain and functional limitation preoperatively, and who often experience substantial improvements postoperatively. The developer notes that the mean and distribution of hospitals' risk-standardized improvement rates ranged from 6.65% to 86.84% (median: 66.49%) (NQF Measure Testing Form, Table 11). The developer further noted an interquartile range or 54.36 – 72.51%, representing a difference of 18 percentage points, and the difference between the 10th and 90th percentiles (20.94% and 78.85%, respectively) was just shy of 58 percentage points (NQF Measure Testing Form, Table 11).
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	The Hospital Inpatient Quality Reporting program does not currently include measures assessing THA/TKA patient reported outcomes. The measure compliments existing outcome measures that are publicly reported on Hospital Compare including CMS' THA/TKA risk-standardized complication rate, THA/TKA risk-standardized readmission rate, and THA/TKA risk-standardized episode of care payment measures. NQF measure #2653: *Average change in functional status following total knee replacement surgery* is an existing clinician group level measure that is similar to this measure. However, this measure is a hospital-level quality measure, utlizes different sources of data, and targets a different population of individuals age 65 and above.
Can the measure be feasibly reported?	Yes	This measure uses Medicare administrative claims-based data. Additionally, PRO data can be collected and utilized by health care personnel during the provision of care. However, the measure developer states that not all clinicians collect patient-reported outcomes on their patients that undergo elective primary THA/TKA procedures. The measure allows hospitals to collect data using both paper and electronic formats, so not all required data elements are electronically collected. Most hospitals participating in the Center for Medicare and Medicaid Innovation (CMMI) Comprehensive Care for Joint Replacement (CJR) model submitting PRO data do not use electronic data capture. Advances in electronic PRO data capture support potential feasibility of an electronic format for this measure in the future, and measure specifications are harmonized with eCQM process measures that incentivize collection of the PRO data needed to calculate the measure outcome. Further, measure guidelines require that hospitals should have at least 25 cases per measurement year.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Yes	The measure is specified and tested at the facility-level of analysis in the hospital inpatient facility setting, aligned with the setting that it is proposed to be utilized in. This is a PRO-PM and the population of measure specification is Medicare fee-for-service (FFS) patients 65 years of age and older undergoing elective primary THA/TKA procedures.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?	N/A	The measure is new and not in current use.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • Total joint arthroplasty is the top procedure within Medicare. Data collection issues: • None Calculation issues: • The threshold of 25 cases may increasingly be an issue over time as more of these procedures are moving to the outpatient setting, leading to a decreasing patient volume within the inpatient setting. This may have a larger impact within rural communities. • Additionally, there was a comment that rural facilities are less likely to have an ambulatory surgical center (ACS), so need to focus more so on outpatient settings, not just ASCs. Unintended consequences: • No issues identified Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 3.1 1 – 0 vote 2 – 4 votes 3 – 8 votes 4 – 6 votes 5 – 0 vote
Preliminary Analysis Recommendation	Support for Rulemaking	
Summary: What is the potential value to the program measure set?	[redacted]	This patient-reported outcome-based performance measure (PRO-PM) aligns with the goal of patient-centered approaches to health care quality improvement and targets high variability in hospital performance. The measure addresses the high priority area of functional outcomes for the Hospital IQR program. The program currently does not include a measure that assesses PROs among THA/TKA patients at the hospital level.

Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	PROs among THA/TKA patients vary across hospitals, suggesting opportunities for improvement in quality of care. The measure seeks to improve patient outcomes following elective primary THA/TKA by providing information to patients, physicians, and hospitals about hospital-level, risk-standardized patient-reported outcomes, such as pain and functional status. This measure is risk-adjusted for patients' comorbid conditions and the goal of the measure is to provide hospitals with performance information in order to implement focused quality improvement efforts.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Yes, under certain circumstances
The Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the development and implementation of patient-reported outcomes performance measures (PRO-PMs) but we also believe that additional questions and work remain before their widespread use such as the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact additional PRO-PMs may have on the reporting of well-established measures such as HCAHPs, and what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other healthcare provider. This measure requires the collection of multiple data points beyond the typical clinical variables to ensure that the performance scores are adequately risk adjusted. The FAH supports the inclusion of these data points but we are concerned that the developer has not provided sufficient information on how these data are collected and what additional workload and time will be required. For example, several of the data elements needed for risk adjustment are derived from patient-reported surveys, which must be collected within 0-90 days pre-operative. No information was provided on the processes used by the hospitals such as whether it required coordination with orthopedic practices or if the burden of the additional data collection was placed on hospital staff on the day of surgery. To what extent did these requirements impact clinical workflows and were additional staff resources required? What additional costs might an individual hospital encounter as a result of implementation of this PRO-PM? Alternatively, from the patient's perspective, did the additional questions seem relevant and was the point in time during which these additional data were collected appropriate? It will also be critical to understand whether there is a potential for individuals to prioritize the completion of one survey over another and therefore lead to negative unintended consequences on response rates for other PRO-PMs such as HCAHPS. Analysis of response rates for HCAHPS from 2008 (33%) to 2017 (26%) revealed a percentage change of -22% overall and an average 0.8 percentage point drop per year (FAH, 2019). This erosion of participation from patients will likely only increase as PRO-PMs become more prevalent. The FAH believes that CMS must develop solutions to these concerns prior to implementation of this measure in the Hospital Inpatient Quality Reporting Program. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation." Reference: Federation of American Hospitals. Modernizing the HCAHPS Survey. Released June 2019. Available

Author	Submitted Comment
	at: https://www.fah.org/fah-ee2-uploads/website/documents/Modernizing_HCAHPS_-Recommendations_from_PELs.pdf.
American Medical Association	The AMA supports the assessment of patient-reported outcomes but believes that the burden of data collection both to the hospital and the patient must be adequately addressed. In the recent NQF endorsement review of this measure, the developer did not adequately assess the feasibility and potential data collection burden to both the hospital and patient. Specifically, the responses to the questions on feasibility do not discuss how the testing sites coordinated data collection across settings or whether the hospital assumed responsibility for the multiple data elements from additional patient-reported surveys used in the risk adjustment approach. This question is particularly important since the specifications require hospitals to collect data for one measure beginning 90 days pre-operatively to up to one-year post-operative. More importantly, the AMA prefers the inclusion of an assessment from the patient's perspective on whether the timing and number of items solicited throughout this process were appropriate and whether they result in survey fatigue. For example, if these data were collected on the morning of the surgery, stress and anxiety could impact responses. Additionally, the number of surveys throughout the pre-, intra-, and post-operative periods may result in incomplete surveys as compared to other surveys such as HCAHPS. We believe that it is critical to understand the potential impact and burden that could be experienced in completing these multiple surveys. While it may seem reasonable for one measure, if this measure is an example of how future measures could be specified, the AMA is concerned about the potential long-term impact on patients and hospitals as more and more patient-reported outcome performance measures are implemented. The AMA believes that additional information on these concerns is needed prior to the MAP recommending this measure. The AMA recommends that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."
Premier	Premier conceptually supports this measure but is concerned about the level of burden associated with data collection. This measure was tested as part of the mandatory Comprehensive Care for Joint Replacement (CJR) Model. Under the model, the measure was voluntary but participants could increase their composite quality score by two points if they successfully reported on the measure. Many model participants found that the burden of data collection outweighed the potential for bonus points. As a result, completion rates for the measure were low. Introducing the measure to all hospitals may result in even more burden, since this type of care may be less of focus for those not participating in the CJR model. CMS should also evaluate and release feedback on the voluntary reported measure under CJR before considering expansion of the measure to all hospitals. As a result, we recommend that CMS not move forward with this measure until it has evaluated voluntary reporting under CJR and the endorsement process has considered the burden associated with this measure.
AdvaMed	AdvaMed strongly supports this measure as it would give the public critical data on THA/TKA patient outcomes experienced at various hospitals across the country. We also ask that if CMS places this measure in the Inpatient Quality Reporting program, that it subsequently assign the measure to Medicare's Value-Based Purchasing program as soon as practicable. This measure would also align with a MIPS physician quality measure on functional improvement after THA and TKA. Because many THA and TKA procedures are moving from hospital inpatient to hospital outpatient settings, we ask that CMS ensure that patients undergoing these procedures in either setting are

Author	Submitted Comment
	included in this measure in order to capture the broadest and most meaningful set of patient outcomes. Further, we ask that CMS post the hospital-specific measure results on Hospital Compare as soon as possible, so that beneficiaries can act as informed consumers when deciding what facility best meets their needs for optimal TKA or THA outcomes.
America's Essential Hospitals	CMS recently finalized policies to eliminate the inpatient only (IPO) list over the next three years. Along with physician judgement, the IPO list is a tool to indicate which services are appropriate to furnish in the outpatient setting. Eliminating the IPO list will cause a significant shift in care settings for various procedures, as we already saw with removal of total hip/total knee arthroplasty (THA/TKA) in 2018. As noted under the rationale for the patient-reported outcome (PRO) measure for THA/TKA, "optimal clinical outcomes depend not just on the surgeon performing the procedure, but also on: the entirety of the team's efforts in the care of the patient; care coordination across provider groups and specialties; and the patients' engagement in their recovery." Another factor to consider is the patient population receiving inpatient care. We know there are differences in patient population for THA/TKA outpatient procedures—i.e., younger, active, fewer complications, and more support at home than most Medicare beneficiaries. Further, many Medicare and essential hospital patients have comorbidities and would require intensive rehabilitation after a THA/TKA procedure; this rehabilitative care is best performed in an inpatient setting. Outcome measures for these procedures should be appropriately adjusted to reflect the shift of less complex procedures to the outpatient setting. Additionally, there are barriers to PRO measurement, including administration in vulnerable populations, literacy, health literacy, and language and cultural differences. Patient populations served by essential hospitals include those with lower education or income, as well as racial and ethnic minorities. Limited health literacy might be more prevalent in these groups and could impact understanding or interpretation of the questions included in a PRO measure. We urge CMS to further examine the impact these barriers might have on PRO measurements among vulnerable populations, including people with limited health literacy, before including in CMS programs.
American College of Surgeons	On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the Measure Applications Partnership (MAP). The ACS is a scientific and education association of surgeons founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. ACS has a vested interest in CMS' MAP and the CMS Measures Under Consideration (MUC) list because of our dedication to improving the value of care for surgical patients. With our 100-year history in developing quality programs to optimize the delivery of surgical services, we believe that we can offer valuable insight to the MAPs deliberations. The ACS supports the inclusion of the Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (MUC20-0003) in the Hospital Inpatient Quality Reporting (IQR) Program. Using joint-specific patient-reported outcome measures (PROMs) to measure hip or knee pain and functioning following a Total Hip (THA) and Total Knee Arthroplasty (TKA) procedure are highly effective in measuring a patient's post-operative goals. THA and TKA procedures are unique from some other surgical procedures (such as cancer surgeries) because the improvements in a patient's joint-function and the presence

Author	Submitted Comment
	of pain can be clearly tracked through the pre-operative and post-operative phases of care. Utilizing PROMs that focus solely on patients' post-operative goals and outcomes becomes more complicated when measuring outcomes in other specialties such as oncological care, where improvement metrics are influenced by many other factors that are unique to the specific patient's condition. There are not clear goals and metrics that can be applied to all patients that undergo these treatments, instead PROs are more focused on the patient's experience while receiving treatment. It is the ACS' hope that functional PROMs will become more commonplace in other surgical specialties, as they are appreciated by both the patient and the surgical team. In past years, the ACS has advocated for the use of functional PROMs in CMS programs, because they can more accurately measure the success of the procedures based on outcomes that are important to the patients, while also supplying the clinical team with information essential to the patients recovery. Measuring patient-reported outcomes (PROs) gives the patient the opportunity to determine whether their care goals have been met, share their post-surgical experience, and provide meaningful, actionable data for the surgical team. PROs tailored to a condition or episode allow clinicians to better understand the elements of care their patients value most and empower patients to work with care teams to communicate goals and engage in shared decision making prior to and during care. Continuing the use of PROs in CMS programs will reflect a transition to a more patient-centric program by assessing outcomes that matter most to patients. Also critical for a patient-centric approach is to include this measure in the clinician programs, such as MIPS and/or MVPs. One way to consider alignment of PROs at the clinician and facility level is to measure whether the facility has the infrastructure to measure a specific PRO, and then then clinician can be measured based on a quality improvement plan to follow up on the responses to the same PRO.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Cerner Corporation	Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) Implementation of PROM will improve patient care and health care providers performance, increasing their accountability. Tracking patients progress provide data that can be used to make better care decisions, more effective and aligned with patient's needs. Related to the implementation, we recommend adding to the exclusion criteria those conditions that could impact patient's progress as hip/pelvis fractures
Association of American Medical Colleges (AAMC)	The Hospital MAP supported the Total Hip/Knee Arthroplasty patient-reported outcomes (PRO) measure (MUC2020-003) for future rulemaking. While the AAMC wholeheartedly supports the movement towards patient-centered approaches to quality measurement, we believe that there is need for more evaluation of the survey fatigue on patients and the interaction of the measure's survey instrument with the Consumer Assessment of Healthcare Providers and Systems (CAHPS) surveys. The CAHPS survey has seen declining response rates over the past several years, and it begs the question whether incorporating another survey-based measure into federal quality

Author	Submitted Comment
	programs could further erode such response. There was some discussion by the Hospital MAP of whether it is feasible to examine response rates across the two patient survey measures to assess such fatigue. The AAMC recommends that the MAP recommendation be conditional support for rulemaking based on evaluation of the measure's interaction and impact on CAHPS.
American Medical Association	The American Medical Association (AMA) continues to be concerned that the burden of data collection both to the hospital and the patient has not been adequately addressed. In the recent NQF endorsement review of this measure, the developer did not adequately assess the feasibility and potential data collection burden both to the hospital and patient. We believe that it is critical to understand the potential impact and burden that could be experienced. While it may seem reasonable for one measure, if this measure is an example of how future measures could be specified, what is the potential long-term impact on patients and hospitals as more and more patient-reported outcome performance measures are implemented? The AMA believes that additional information on these concerns is needed and requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."
American Hospital Association	The AHA agrees with the MAP's position of Support for this measure, and offers recommendations to CMS on its implementation in the IQR. We believe that the measure concept is appropriate for a CMS quality program because it addresses a common procedure that is performed nationwide on a variety of patients, making it relevant for a large population. In addition, elective procedures like THA/TKA are considered "shoppable" services, where prospective patients can use comparable performance information to make a choice on where to get care. Finally, the outcome of note (substantial clinical benefit) is comprehendible and aligned with patient values—more so than many currently used measures that provide clinical insight into complex issues that a layperson would have trouble understanding. These conceptual advantages coupled with the measure's NQF endorsement make it appropriate for inclusion in a CMS quality reporting program. However, there are a few caveats we encourage CMS to consider and address before proposing this measure in the next rulemaking cycle. The first is that CMS itself as well as many private payers are increasingly encouraging THA/TKA procedures to be done on an outpatient basis; CMS removed THA from the Inpatient-Only List in the CY 2020 OPPS final rule and added TKA to the ASC Covered Services List in the same rule. Soon, the patients receiving these services in an inpatient setting will be the sickest and most complex (i.e., patients who will need access to the full resources of a general acute care hospital rather than an ambulatory surgical center or other outpatient facility). Some facilities that see a major shift in volume to outpatient might have trouble amassing the minimum 25 cases necessary to calculate measure performance. In addition, the time lag between care being delivered and data being reported is more substantial for this measure than for most as the postoperative assessment is not conducted until up to a year after the procedure. These issues undermine the usefulness of the measure by resulting in inappropriate comparisons. AHA is supportive of well-constructed and meaningful patient-reported outcomes measures. While helpful, these measures are inherently burdensome to patients, and we urge CMS to consider how this and other PROs will interact with (and potentially compete with) other patient surveys, like the HCAHPS survey. Patient response rates to the various surveys across the continuum of care are dropping, and the more tasks heaped upon patients, the less likely they are to complete them all.

Author	Submitted Comment
	Thus we encourage CMS to be thoughtful in their implementation of this measure to ensure that it gleans sufficient data to inform quality improvement.
Federation of American Hospitals	The Federation of American Hospitals (FAH) continues to have concerns with the potential implementation of this measure. Specifically, the FAH believes that additional questions and work remain before its widespread use such as the degree to which multiple PRO-PMs could lead to survey fatigue for patients, the potential impact additional PRO-PMs may have on the reporting of well-established measures such as HCAHPs, and what level of data collection burden for an individual PRO-PM is acceptable for a hospital or other healthcare provider. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."
AdvaMed	AdvaMed strongly supports this measure as it would give the public critical data on THA/TKA patient outcomes experienced at various hospitals across the country. We also ask that if CMS places this measure in the Inpatient Quality Reporting program, that it subsequently assign the measure to Medicare's Value-Based Purchasing program as soon as practicable. This measure would also align with a MIPS physician quality measure on functional improvement after THA and TKA. Because many THA and TKA procedures are moving from hospital inpatient to hospital outpatient settings, we ask that CMS ensure that patients undergoing these procedures in either setting are included in this measure in order to capture the broadest and most meaningful set of patient outcomes. Further, we ask that CMS post the hospital-specific measure results on Hospital Compare as soon as possible, so that beneficiaries can act as informed consumers when deciding what facility best meets their needs for optimal TKA or THA outcomes.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0004
Other Measure Identification Numbers	N/A
Title	Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)
Program	Hospital Outpatient Quality Reporting Program
Workgroup	MAP Hospital
In what state of development is the measure?	Fully Developed
State of Development Details	Alpha testing is complete. Alpha testing findings include 8,051 cases of STEMI for patients aged 18 years and older treated in the ED in 2016. Of these cases, 3,512 (43.6%) were attributable to a facility; there were 169 unique facilities identified. Although not all cases were linked to a specific facility, we were able to evaluate all cases in aggregate for feasibility assessments. Field testing of the measure is complete. As part of field testing, Lewin contracted with two sites, which use two differing EHR vendors (EPIC and Cerner). Lewin interviewed nine staff across the two sites to discuss current practices of care as they relate to the measure concept (specifically face validity, feasibility, and usability of the measure). All participants stated the measure appropriately assesses quality of care, as it incorporates evidence-based and established standards into the specifications. Participants from both sites indicated that the measure's results would be useful and are consistent with internal performance metrics currently in use. Respondents indicated that they did not foresee any negative unintended consequences to measure implementation, other than potential changes in workflow necessary to capture some of the data elements. Though interview participants from both sites believe that the face validity, feasibility, usability, and attribution of the STEMI eCQM were adequate, the testing identified potential measure refinements several of which we incorporated into the measure, such as removing an exclusion for hypertension that was non-specific (these changes are not reflected in quantitative testing, but improve the measure's reliability and validity). Quantitative testing at the contracted sites included EHR data extraction and comparison to manual chart abstraction data, with standard metrics of reliability and data element validity. Lewin collected data for 1,163 cases from the EHR extract and 220 manually chart-abstracted cases from both sites (110 cases manually abstracted from each site to support a minimum threshold of 0.41 for Cohen's kappa. Quantitative data show moderate agreement between the EHR extract and chart-abstracted data, though magnitude of agreement varies by data element. For testing site 1 (n=110), kappa values average 0.51 (standard deviation [S.D.] 0.49) across denominator exclusion data elements with a range from -0.02 to 1.00 (please see STEMI eCQM Data Element Agreement attachment for data element specific values). Average sensitivity for exclusion data elements is 0.54 (standard deviation [S.D.] 0.49) with a range of 0.00 to 1.00. Average positive predictive value (PPV) for exclusion data elements is 0.84 (S.D. 0.36) with a range of 0.00 to 1.00. Average specificity for these data elements is 1.00 (S.D. 0.01) with a range of 0.94 to 1.00 and average negative predictive value (NPV) is 0.99 (S.D. 0.02) with a range of 0.92 to 1.00. Kappa values for numerator data elements average to 0.34 (S.D. 0.38) and range from -0.02 to 0.74. Average sensitivity for numerator data elements is 0.45(S.D. 0.40) with a range of 0.00 to 0.76. Average PPV for numerator data elements is 0.60 (S.D. 0.53) with a range of 0.00 to 1.00. Average specificity for these data elements is 0.84 (S.D. 0.26) with a range of 0.54 to 1.00. Average NPV is 0.81 (S.D. 0.29) with a range of 0.47to 0.98. For testing site 2 (n=110), kappa values average to 0.73 (S.D. 0.44) for denominator exclusion data elements and range from 0.00 to 1.00. Average sensitivity is 0.89 (S.D. 0.30) with a range of 0.00 to 1.00. Average PPV for exclusion data elements is 0.83 (S.D. 0.37) with a range of 0.00 to 1.00.

	Average specificity for these data elements is 0.98 (S.D. 0.05) with a range of 0.93 to 1.00 and average NPV is 0.99 (S.D. 0.02) with a range of 0.95 to 1.00. Kappa values for numerator data elements average to 0.69 (S.D. 0.54) and range from 0.00 to 1.00. Average sensitivity is 0.73 (S.D. 0.46) with a range of 0.20 to 1.00. Average PPV for numerator data elements is 1.00 (S.D. 0.00 with no range). Average specificity for these data elements is 1.00 (S.D. 0.00 with no range). Average NPV is 0.72 (S.D. 0.48) with a range of 0.16 to 1.00. Data element specific values can be found in the Agreement attachment.
Measure Description	The percentage of emergency department (ED) patients with a diagnosis of ST-segment elevation myocardial infarction (STEMI) who received appropriate treatment. The measure will be calculated using electronic health record (EHR) data and is intended for use at the facility level.
Numerator	ED STEMI patients whose time from ED arrival to fibrinolysis is 30 minutes or fewer OR Non-transfer ED STEMI patients who received percutaneous coronary intervention (PCI) at a PCI-capable hospital within 90 minutes of arrival OR ED STEMI patients who were transferred to a PCI-capable hospital within 45 minutes of ED arrival at a non-PCI capable hospital.
Denominator	ED patients with STEMI who should have received appropriate treatment for STEMI
Exclusions	Denominator Exclusions. The following conditions exclude patients from the measure if they appear as Active in the EHR at the time of the ED encounter: Mortality in the ED; Active bleeding or bleeding diathesis (excluding menses); Intracranial or intraspinal surgery; Ischemic stroke; Known malignant intracranial neoplasm (primary or metastatic); Known structural cerebral vascular lesion (e.g., AVM); Significant facial and/or closed head trauma, intracranial hemorrhage, or other known intracranial pathology; Suspected aortic dissection; Active peptic ulcer; Cardiopulmonary arrest; For streptokinase/anistreplase: prior exposure or prior allergic reaction to these agents; Intubation Oral anticoagulant therapy; Patients with advanced dementia; Pregnancy; Internal bleeding; Major surgery; Severe neurologic impairment (based on Glasgow coma scale).
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	N/A
Year of next anticipated NQF CDP endorsement review	Not applicable
Year of most recent NQF Consensus Development Process (CDP) endorsement	Not applicable
Is the measure being submitted exactly as endorsed by NQF?	Not applicable
If not exactly as endorsed, describe the nature of the differences	N/A

What data sources are used for the measure?	EHR
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	Facility
In which setting was this measure tested?	Emergency department
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Healthcare-associated infections
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Make care safer by reducing harm caused in the delivery of care
What secondary healthcare priority applies to this measure?	Promote effective communication and coordination of care
What area of specialty best fits the measure?	Emergency Medicine
What is the target population of the measure?	Medicare Fee for Service
Is this measure an eCQM?	Yes
If eCQM, enter Measure Authoring Tool (MAT) number	CMS996
If eCQM, does the measure have a Health Quality Measures	Yes

Format (HQMF) specification?	
Comments	Additional specialties (Question/Row 22): Cardiology and Hospitalist
Measure steward	Centers for Medicare & Medicaid Services
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Crenshaw, P. Nicole; CMS; (410) 786-5470; pnicole.crenshaw@cms.hhs.gov
Primary Submitter Contact Information	McKierna Altaf, Faseeha; Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE); 860-752-5471; Faseeha.Altaf@yale.edu
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	Johnson-DeRycke, Rachel; Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (YNHHSC/CORE); 860-324-0218; rachel.johnson-derycke@yale.edu
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	Not applicable
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP	N/A

workgroup(s) in each year	
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	Feasibility scorecard is attached.
How is the measure expected to be reported to the program?	eCQM
Is this measure similar to and/or competing with measure(s) already in a program?	Yes
Which existing measure(s) is your measure similar to and/or competing with?	Fibrinolytic Therapy Received within 30 Minutes of ED Arrival (OP-2); Median Time to Transfer to Another Facility for Acute Coronary Intervention (OP-3)
How will this measure be distinguished from other similar and/or competing measures?	The STEMI eCQM expands on the timeliness of care issues addressed by two Hospital Outpatient Quality Reporting (OQR) Program measures—OP-2 (Fibrinolytic Therapy Received within 30 Minutes of Emergency Department Arrival) and OP-3 (Median Time to Transfer for Acute Coronary Intervention) quality measures. The STEMI eCQM addresses effective and appropriate treatment in a timely manner using data captured in the EHR and reported electronically.
Rationale for how this measure will add to the CMS program	Use of the eCQM could reduce burden on facilities currently measured using two chart-abstracted measures (OP-2 and OP-3) and broaden the population for which performance scores could be publicly reported.
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A

Evidence of performance gap	Guidelines recommend use of PCI or fibrinolysis to treat STEMI (O'Gara et al., 2013). Studies suggest improvements over time in the timeliness of delivery of appropriate revascularization treatments for patients presenting to the ED with STEMI, and there has been a shift over time of the preferred reperfusion strategy from fibrinolysis to PCI (Hira et al., 2016; Liu et al., 2015). However, several important gaps remain. For example, most of the improvements have been made in door-to-balloon times for PCI. However, timely PCI is frequently not an option for patients seeking care at rural or critical access facilities, where fibrinolysis or transfer to a PCI facility remain the dominant approach to revascularization. Delays persist in all three treatment strategies, especially transfer for PCI, and to some extent, fibrinolytics. A 2016 retrospective study by Hira et al. of patients with STEMI who underwent reperfusion therapy assessed trends in STEMI care between January 1, 2003 and December 31, 2008. Researchers identified 29,190 patients, of whom 2,441 (8.4%) received fibrinolysis; for these patients, 38.2% had fibrinolytic therapy administration occur within 30 minutes. These results align with outcomes from a 2015 study, which found that approximately 50% of patients who were eligible for fibrinolytic therapy received it; of this population, only about 30% had their administration occur in accordance with clinical practice guideline recommendations (Vora et al.). The median door-to-needle time for patients receiving fibrinolysis in advance of transfer to another facility for PCI was 34 minutes, falling slightly outside the recommended window. Performance data from CMS on OP-2 suggest there is an opportunity for facilities to improve the appropriate treatment for patients with STEMI who received fibrinolytic therapy in the ED. The data indicate that, while facility-level OP-2 scores have improved since the measure was first implemented in the CMS Hospital OQR Program in 2010, performance is still highly variable. During the April 20102012–March 20112013 data collection period, performance scores ranged from 90% to 100%, with a weighted mean of 65.259.1% (that is, on average, 65.259.1% of STEMI patients who received fibrinolytic therapy did so within 30 minutes of ED arrival). For the April 2018 through March 2019 data collection period, performance scores also ranged from 14% to 100%, with the weighted mean rising to 70.4%. This translates to a 7.919.1% (or 6.2%)11.3 percentage points) improvement in the weighted mean of OP-2 performance scores from April 20102012 to March 2019. Performance data from CMS on OP-3 suggest there is an opportunity for facilities to improve the median time to transfer for acute coronary intervention. Though data indicate that, while facility-level OP-3 scores have improved since the measure was first implemented in the CMS Hospital OQR Program in 2010, performance is still highly variable. During the April 2012–March 2013 data collection period, performance scores ranged from 9 to 161 minutes, with a weighted mean of 62.73 (that is, on average, 62.73 minutes passed from the time of ED admission to transfer for acute coronary intervention). For the April 2018 through March 2019 data collection period, performance scores ranged from 19 minutes to 106 minutes, but the weighted mean decreased to 54.22 minutes. This translates to an 8.51-minute decrease (or 15.7 percentage points) in the weighted mean of OP-3 performance scores from April 20102012 to March 2019. For patients presenting to hospitals with primary PCI capabilities, door-to-balloon (D2B) time has shown marked improvements over time, and most hospitals are able to deliver PCI within 90 minutes of patient arrival. The median time to primary PCI in the National Cardiovascular Data Registry in 2014 was 59 min (10th, 50th, and 90th percentiles of 70, 60, and 48 min, respectively) (Masoudi et. al., 2017). In addition to improving adherence to treatment recommendations from clinical practice guidelines, public reporting of an eCQM on appropriate care for STEMI patients in the ED could also help to identify disparities in care for certain patient populations. Analyses performed by Lewin using 2014 data submitted to CMS's clinical data warehouse (CDW) examined the impact of patient and facility characteristics using a logistic regression model for 3,844 cases. When compared to patients treated in facilities with fewer than 50 beds (a proxy for facility size), patients treated in facilities with 101 to 250 beds (OR=1.74, p=0.002) and 251 to 500 beds (OR=2.02, p=0.017) were significantly more likely receive fibrinolytic therapy within 30

	minutes of ED arrival. Patients aged 40 to 50 (OR=3.80, p=0.03), 50 to 60 (OR=3.85, p=0.03), 60 to 70 (OR=3.44, p=0.04), and 70 to 80 (OR=3.10, p=0.06) were significantly more likely than patients aged 18 to 30 to receive fibrinolytic therapy within 30 minutes of ED arrival. African-American patients were significantly less likely than their white peers to receive fibrinolytic therapy within 30 minutes of ED arrival (OR=0.60, p=0.001), as were Hispanic patients (OR=0.65, p=0.03), when compared to those patients of non-Hispanic origin. Finally, female patients were less likely than male patients receive fibrinolytic therapy within 30 minutes of ED arrival (OR=0.77, p< 0.001). There is an opportunity for a new publicly reported eCQM to address these existing gaps and potentially improve care and health outcomes. References: Hira RS, Bhatt D, Fonarow GC, Heidenreich PA, Ju C, Virani S, Bozjurt B, Petersen LA, Hernandez AF, Schwamm LH, Eapen ZJ, Albert MA, Liang L, Matsouaka RA, Peterson ED, & Jneid H. (2016). Temporal trends in care and outcomes of patients receiving fibrinolytic therapy compared to primary percutaneous coronary intervention: insights from the get with the guidelines coronary artery disease (GWTD-CAD) registry. Journal of the American Heart Association, 5(10). Available at https://www.ncbi.nlm.nih.gov/pubmed/27792640. Liu F, Guo Q, Xie G, Zhang H, Wu Y, & Yang L. (2015). Percutaneous coronary intervention after fibrinolysis for ST-segment elevation myocardial infarction patients: An updated systematic review and meta-analysis. PLoS One, 10(11):e0141855. Available at https://www.ncbi.nlm.nih.gov/pubmed/26523834. Masoudi FA, Ponirakis A, de Lemos JA, Jollis JG, Kremers M, Messenger JC, Moore J, Moussa I, Oetgen WJ, Varosy PD, Vincent RN, Wei J, Curtis JP, Roe MT & Spertus JA (2017). Trends in U.S. Cardiovascular Care: 2016 Report From 4 ACC National Cardiovascular Data Registries. Journal of the American College of Cardiology, 69(11), 1427–1450. Available at: https://doi.org/10.1016/j.jacc.2016.12.005. Vora A, Holmes M, Rokos I, Roe T, Granger C, French W, Antman E, Henry T, Thomas L, Bates E, Wang T. (2015). Fibrinolysis use among patients requiring interhospital transfer for ST-segment elevation myocardial infarction care: A report from the US national cardiovascular data registry. JAMA Internal Medicine, 175(2): 207-215. Available at: https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1984250.
Unintended consequences	A possible unintended consequence of the measures use there may be the potential for providers to inappropriately expedite treatment to score favorably on the measure, increasing the risk for harm.
Which clinical guideline(s)?	This electronic clinical quality measure (eCQM) supports compliance with the 2013 American College of Cardiology Foundation and American Heart Association (ACCF/AHA) clinical practice guidelines for the management of STEMI by measuring appropriateness and effectiveness of care for STEMI patients in the ED based on the standards of care. Implementing this eCQM has the potential to improve the delivery of care, support adherence and alignment with current clinical practice guidelines, and reduce adverse health outcomes (e.g., mortality, bleeding events, and reinfarction). The 2013 ACCF/AHA clinical practice guidelines are evidence-based. In cases where there were inadequate data, recommendations were made using expert consensus.
Briefly describe the peer reviewed evidence justifying this measure	Studies have shown that delays in the treatment of acute myocardial infarction (AMI) leads to increased risk of in-hospital mortality and morbidity, with nearly two lives per 1,000 patients lost per hour of delay in treatment (Sohlpour & Yusuf, 2014; Fibrinolytic Therapy Trialists' Collaborative Group, 1994). For the fibrinolytic therapy treatment arm, the American Heart Association (AHA) estimates that 65 lives will be saved per 1,000 patients if treatment is administered within the first hour of symptom onset, and 131 lives will be saved per 1,000 patients treated if fibrinolytic therapy is delivered within the first three hours (O'Connor et al., 2010). The total ischemic time—that is, the time from onset of STEMI symptoms to the initiation of some form of reperfusion therapy—is the principal determinant of health outcomes for patients with an AMI, so timely care is essential to minimize effects of disease morbidity and reduce mortality for this population. Primary PCI is the preferred treatment approach, with guidelines recommending initiation of PCI within

	120 minutes from first medical contact (O'Gara et al., 2013). In situations where it is unlikely or impossible for a patient to receive primary PCI within the 120-minute timeframe, fibrinolytic therapy may be used for reperfusion and should be rapidly administered to reduce mortality and minimize morbidity; guidelines recommend that fibrinolytic therapy administration occur within 30 minutes of hospital arrival; this may also require rapid transfer for PCI (O'Gara et al., 2013). References: O'Connor RE, Brady W, Brooks SC, Diercks D, Egan J, Ghaemmaghami C, Menon V, O'Neil BJ, Travers AH, Yannapoulos D. (2010) Part 10: Acute coronary syndromes: 2010 American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation, 122(suppl 3): S787-S817. DOI: 10.1161/CIRCULATIONAHA.110.971028. O'Gara P, Kushner F, Ascheim D, Casey D, Chung M, de Lemos J, Ettinger S, Fang J, Fesmire F, Franklin B, Granger C, Krumholz H, Linderbaum J, Morrow D, Newby L, Ornato J, Ou N, Radford M, Tamis-Holland J, Tommaso C, Tracy C, Woo Y, Zhao D, Anderson J, Jacobs A, Halperin J, Albert N, Brindis R, Creager M, DeMets D, Guyton R, Hochman J, Kovacs R, Kushner F, Ohman E, Stevenson W, Yancy C. (2013). 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation, 127(4): e362-425. Available at https://www.ncbi.nlm.nih.gov/pubmed/23247304.

Preliminary Analysis – MUC ID: MUC20-0004 Appropriate Treatment for ST-SEgment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED)

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This measure addresses the Meaningful Measure Areas and Hospital OQR Program priorities of "Effective Prevention and Treatment" and "Promote Effective Communication and Coordination of Care". This measure assesses concepts similar to existing measures "Fibrinolytic Therapy Received within 30 Minutes of Emergency Department Arrival" and "Median Time to Transfer for Acute Coronary Intervention" (OP-2 and OP-3, respectively) in the Hospital OQR Program, but may ease burden of measurement by using an electronic data source.
Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	Yes	This is a process measure addressing timely treatment of ST-Segment Elevation Myocardial Infarction (STEMI), which has been shown to reduce mortality (Gibson et al. 2020). The developer cites 2013 guidelines in which primary PCI is the preferred treatment approach, with the initiation of PCI within 120 minutes from first medical contact or fibrinolytic therapy administration occurring within 30 minutes of hospital arrival in situations where PCI is unlikely or impossible (O'Gara et al. 2013). MAP should consider if the evidence submitted by the developer includes time windows that align with the proposed measure. The developer cites additional evidence that the implementation of quality measures for the timeliness of fibrinolytic therapy and acute coronary intervention delivery have improved adherence to clinical practice guidelines and recommendations.

Does the measure address a quality challenge?	Yes	550,000 new cases of myocardial infarction and 200,000 recurrent cases are estimated to occur in the United States annually, with approximately 38% of acute coronary syndrome presentations due to ST-elevation myocardial infarction (Akbar et al. 2020). A 2015 study was cited that found approximately 50% of patients who were eligible for fibrinolytic therapy received it; of this population, only about 30% had their administration occur in accordance with clinical practice guideline recommendations. Further, the developer notes significiant performance variation in OP-3 median time to transfer for acute coronary intervention ranging from 9 to 161 minutes passed from the time of ED admission to transfer for acute coronary intervention. The developer cites evidence that the implementation of existing quality measures OP-2 and OP-3 have improved adherence to the recommended timing guidelines for treatment.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	The measure covers the measure focus area of two existing Hospital OQR Program measures, “Fibrinolytic Therapy Received within 30 Minutes of Emergency Department Arrival” (OP-2) and “Median Time to Transfer for Acute Coronary Intervention” (OP-3), and combines both of these treatment options along with a third option to transfer patients to a PCI-capable facility. This measure is a complement to these existing measures since it is an eCQM and is proposed as a less burdensome alternative to using two separate, chart-based quality measures to evaluate appropriate treatment for STEMI. This measure is not currently used in any CMS programs.
Can the measure be feasibly reported?	Yes	The measure is fully specified and the developer notes that it has undergone alpha testing, face validity testing, feasibility testing, and usability testing. The measure is an EHR-based eCQM.
Is the measure applicable to and appropriately specified for the program’s intended care setting(s), level(s) of analysis, and population(s)?	Yes	The measure is fully developed and specified for the facility-level care setting.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	Yes	The measure is not in current use. The developer identified that a possible negative unintended consequence could be providers inappropriately expediting treatment to achieve better scores.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	

Hospice High Priority Areas	N/A	
Rural Workgroup Input	[redacted]	Relative priority/utility: • There was some discussion regarding the appropriate treatment time and how this may be impacted in rural settings given transportation issues, specifically with getting someone to a PCI capable hospital in 90 minutes. • The developer clarified that if it is an on-site facility that can do PCI, the treatment modality is PCI, otherwise, providers can use fibrinolysis or can transfer to a hospital that provides PCI. For transfer, it is not only the 90 minutes if you are not a PCI hospital. The transfer process starts 45 minutes out. If it is an on-site PCI hospital, then time to PCI should be 90 minutes. Data collection issues: • None Calculation issues: • None Unintended consequences: • None identified Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.0 1 – 0 vote 2 – 0 vote 3 – 4 votes 4 – 10 votes 5 – 3 votes
Preliminary Analysis Recommendation	Conditional support for rulemaking	Conditional support for rulemaking is recommended pending NQF endorsement.

Summary: What is the potential value to the program measure set?	[redacted]	The measure addresses the Meaningful Measure Areas and Hospital OQR Program priorities of "Effective Prevention and Treatment" and "Promote Effective Communication and Coordination of Care". This eCQM is a combination of two existing chart extracted measures in the Hospital OQR Program set, "Fibrinolytic Therapy Received within 30 Minutes of Emergency Department Arrival" (OP-2) and "Median Time to Transfer for Acute Coronary Intervention" (OP-3) and includes a third option to transfer patients to a PCI-capable facility. The developer states that the inclusion of this eCQM could reduce data collection burden from the previous chart-based measure collection.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	550,000 new cases of myocardial infarction and 200,000 recurrent cases are estimated to occur in the United States annually, with approximately 38% of acute coronary syndrome presentations due to ST-elevation myocardial infarction (STEMI) (Akbar et al. 2020). The addition of this EHR-based quality measure can improve adherance to fibrinolytic therapy in accordance with clinical practice guideline recommendations and median time to transfer for acute coronary intervention. MAP should consider if the evidence submitted by the developer includes time windows that align with the proposed measure. Additionally, the NQF endorsement process should evaluate the EHR feasibility, reliability, and validity testing conducted by the developer. Conditional support for rulemaking is recommended pending NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Yes, under certain circumstances
Federation of American Hospitals	The Federation of American Hospitals (FAH) recognizes the need to address this important clinical area but encourages the MAP to conditionally recommend this measure until it receives NQF endorsement. The FAH notes that one of the components was previously endorsed by NQF, #288, Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. Endorsement was removed due to concerns with the measure specifications, specifically how the population was defined and the exclusions. A condition should be placed on any recommendation for this measure to ensure that these concerns were adequately addressed. In addition, the FAH also strongly encourages CMS to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) and determine if the measure is reliable and valid across a broader set of EHRs vendors and hospitals. Assessment of how the measure performs using only two systems and two hospitals should not be considered sufficient.
American Medical Association	The AMA believes that additional testing across a wider set of electronic health record systems (EHRs) and hospitals should be conducted on this measure prior to implementation in any programs. In addition, we note that one component of this measure was previously endorsed by NQF – #288, Fibrinolytic Therapy Received Within 30 Minutes of ED Arrival. Endorsement was removed due to concerns with the measure specifications, specifically, the population and exclusions. CMS should ensure that those concerns are addressed, and this measure should be

	endorsed by NQF prior to implementation in any program. The AMA recommends that the highest level of MAP recommendation be "Conditional Support" with the two conditions outlined above.
AdvaMed	AdvaMed strongly supports this measure, as it would provide useful information to support the development of new algorithms for early diagnosis and therapeutic guidance for STEMI.
The Society for Cardiovascular Angiography and Interventions (SCAI)	January 6, 2021 National Quality Forum Measure Application Partnership VIA NQF WEBSITE On behalf of the Society for Cardiovascular Angiography and Interventions (SCAI), I am writing to recommend two preliminary items contained on the 2020-2021 Measure Under Consideration (MUC) list published and released by the Centers for Medicare and Medicaid Services (CMS) on December 21, 2020. Specifically, we are highly supportive of the following two Measures Under Consideration: • Appropriate Treatment for ST Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED), and • Risk-Standardized Acute Unplanned Cardiovascular Related Admission Rates for Patients with Heart Failure for the Merit-based Incentive Payment System The Society for Cardiovascular Angiography and Interventions (SCAI) is a non-profit professional association with over 5,000 members representing the majority of practicing interventional cardiologists and cardiac catheterization teams in the United States, including those providing percutaneous coronary interventions (PCI). SCAI promotes excellence in invasive and interventional cardiovascular medicine through education, representation and the advancement of quality standards to enhance patient care. SCAI diligently participated in the development of these MUCs, working in cooperation with the American College of Cardiology (ACC), the American Heart Association (AHA) and others. SCAI members added the experience, expertise, clinical judgment and especially the value of those physicians that have earned the FSCAI and MSCAI specialty designations to this important work. Only after completing the rigors of medical school, three years of training in internal medicine, 3 more years of training in cardiology and 1 to 2 years of additional cardiology specialization is the value of the SCAI designation is earned. We believe that adding this measure to the MUC list will add value and improve patient outcomes that will likely become a de facto standard of care in this highly complex area. We stand ready to work with you and the Centers for Medicare and Medicaid Services (CMS) to ensure that the benefits of these measures do not outweigh the burden of data collection and reporting now and throughout the challenging process of implementation. We also pledge to continue to provide our experience and expertise related to Quality Improvement, certification and recognition, regulatory and accreditation, public reporting, disease surveillance and adequate payment, to this critical process. As you review these MUC list items and provide input into Medicare programs, including the Merit-based Incentive Payment System (MIPS) and Medicaid Savings Programs (MSSP), please consider SCAI and its members as a critical resource that remains available to you at any time. Please contact Emily Senerth, Senior Manager, Clinical Documents & Quality, should you have questions.

Sincerely,

Cindy Grines, MD MSCAI
President, SCAI

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Cerner Corporation	Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) Patients in the Emergency Department (ED) Replacing the current chart-abstracted OP measures with this eCQM will reduce burden of data collection for HOQR program. We don't anticipate major challenges with the implementation on the measure.
Association of American Medical Colleges (AAMC)	The Hospital MAP conditionally supported for rulemaking the appropriate treatment for STEMI patients process measure (MUC2020-0004) pending NQF endorsement. In general, the AAMC believes that quality measurement should move towards outcomes-based measurement. However, we acknowledge the value of process measures to improve adherence to clinical practice recommendations as an important step towards outcomes-based measurement. We agree with the MAP that the NQF-endorsement evaluation will ensure necessary electronic health record feasibility, reliability, and validity testing necessary before the measure is introduced in the OQR. The AAMC agrees with the MAP's recommendation.
American Hospital Association	The AHA agrees with the MAP's conditional support pending NQF endorsement, and also suggests the additional condition of a planned phasing-out of the current OQR measures with which this measure overlaps, OP-2 and 3. Conceptually, we agree that the evidence behind this measure makes sense: the faster patients receive appropriate STEMI care, the better their outcomes will be. The timelines upon which performance is based in the measure's specifications are consistent with clinical guidelines and the data elements are unlikely to be burdensome to glean from EHRs. The concerns we do have with the measure are likely to be addressed in the endorsement process: specifically, whether there is enough of a performance gap to justify including this measure in a streamlined set. According to the data provided by the developer, nationwide performance for the other STEMI-related measures in the OQR has improved immensely in the past decade; this measure may become topped out soon, if it is not already.

	As noted during the MAP meeting, two OQR measures also address timely fibrinolytic therapy or PCI. OP-2, fibrinolytic therapy received within 30 minutes of ED arrival, directly overlaps with this measure. OP-3, median time to transfer to another facility for acute coronary intervention, also overlaps with this measure and had its endorsement removed. These measures are chart-abstracted, which is more burdensome than this e-measure. Thus, we suggest that CMS's proposal to include this measure in the OQR be coupled with a proposal to remove OP-2 and 3 simultaneously.
Federation of American Hospitals	Yes; support for inclusion in the program.
American Heart Association/ American Stroke Association	The AHA strongly supports adoption of this cross-setting measure that can be reported by both referring hospitals and receiving centers with PCI capability. We believe this will place additional emphasis on the importance of each component of the system in achieving optimal times to reperfusion for patients with STEMI. We also appreciate that this measure reports achievement of optimal target times for each of these key intervals, instead of just median times, as CMS has done in the past. For over 15 years, the American Heart Association's national Mission: Lifeline® initiative has worked to advance STEMI systems of care. While we have seen great progress, there is still an opportunity to further improve care and to reduce mortality and morbidity for STEMI patients nationwide. We hope that the MAP will support this measure and that CMS will include it in the HOQR program as soon as possible.
AdvaMed	AdvaMed strongly supports this measure, as it would provide useful information to support the development of new algorithms for early diagnosis and therapeutic guidance for STEMI.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0005
Other Measure Identification Numbers	N/A
Title	Breast Screening Recall Rates
Program	Hospital Outpatient Quality Reporting Program
Workgroup	MAP Hospital
In what state of development is the measure?	Fully Developed
State of Development Details	Beta testing was completed prior to the 2020 MUC list submission. Mean measure performance (10.01% [SD 6.3%]) falls within the targeted recall rate range of 5–12%; however, performance across common percentiles demonstrates variability across facilities. Of the 3,633 facilities analyzed, 112 (3.1%) facilities had a performance value that was statistically significantly different from a mean benchmark value. Statistically meaningful difference was defined as when the facility score fell outside of the confidence interval (± 1.96 standard deviations) for the measure mean (benchmark value). Thus, there are statistically significant differences in performance across facilities for the Breast Screening Recall Rates measure. Reliability was calculated in accordance with the methods described in The Reliability of Provider Profiling: A Tutorial (2009). This approach calculates the ability of the measure to distinguish between the performances of different facilities. The reliability score is estimated using a beta-binomial model, and is a function of the facility's sample size and score on the measure, as well as the variance across facilities. Reliability scores for the Breast Screening Recall Rates measure ranged from 0.36 to 1.00, with a median reliability score of 0.97. This median score is indicative of very strong measure reliability and suggests that this measure is able to identify true differences in performance between individual facilities. Face validity was systematically assessed, via survey, by a multi-stakeholder group of 32 individuals (including 1 patient/patient advocate). Survey results indicate that 75% of respondents support the measure's intent, to assess recall rates to determine appropriate diagnostic imaging for breast cancer detection; 69% of the respondents strongly agree or agree that the measure addresses quality of care.
Measure Description	The Breast Screening Recall Rates measure calculates the percentage of beneficiaries with mammography or digital breast tomosynthesis (DBT) screening studies that are followed by a diagnostic mammography, DBT, ultrasound, or magnetic resonance imaging (MRI) of the breast in an outpatient or office setting within 45 days.
Numerator	Medicare beneficiaries who had a diagnostic mammography study, DBT, ultrasound, or MRI of the breast following a screening mammography or DBT study on the same day or within 45 days of the screening study.
Denominator	Medicare beneficiaries who underwent a screening mammography or DBT study at a facility reimbursed through the Outpatient Prospective Payment System (OPPS).
Exclusions	This measure does not have any exclusions.
Measure type	Outcome
What is the NQF status of the measure?	Never submitted
NQF ID number	N/A
Year of next anticipated NQF CDP endorsement review	Not applicable

Year of most recent NQF Consensus Development Process (CDP) endorsement	Not applicable
Is the measure being submitted exactly as endorsed by NQF?	Not applicable
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	Claims
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	Facility
In which setting was this measure tested?	Ambulatory/office-based care, Hospital outpatient department (HOD)
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Appropriate use of healthcare
What secondary meaningful measure area applies to this measure?	Preventable healthcare harm
What one primary healthcare priority applies to this measure?	Make care affordable
What secondary healthcare priority applies to this measure?	Make care safer by reducing harm caused in the delivery of care
What area of specialty best	Other - Radiology

fits the measure?	
What is the target population of the measure?	Medicare Fee for Service beneficiaries
Is this measure an eCQM?	No
If eCQM, enter Measure Authoring Tool (MAT) number	Not applicable
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	Not applicable
Comments	N/A
Measure steward	Centers for Medicare & Medicaid Services
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Crenshaw, P. Nicole; CMS; (410) 786-5470; pnicole.crenshaw@cms.hhs.gov
Primary Submitter Contact Information	McKiernan, Colleen; The Lewin Group; (703) 269-5595; colleen.mckiernan@lewin.com
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	Joyce, Erin; Joyce, erin.joyce@yale.edu
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	Not applicable
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not	N/A

recommended in those year(s)?	
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	Breast Screening Recall Rates is a claims-based measure. CMS calculates Outpatient Imaging Efficiency measures using data from final claims that facilities submit for Medicare beneficiaries enrolled in Medicare fee-for-service. Data would be calculated only for facilities paid through the OPPS. At the time of retirement, 3,313 facilities were eligible to report OP-9. We anticipate the number of facilities eligible to report the Breast Screening Recall Rates will be greater than OP-9 as the denominator criteria is more broad.
How is the measure expected to be reported to the program?	Claims
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A

How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Mean measure performance (10.01% [SD 6.3%]) falls within the targeted recall rate range of 5–12%; however, performance across common percentiles demonstrates variability across facilities. Of the 3,633 facilities analyzed, 112 (3.1%) facilities had a performance value that was statistically significantly different from a mean benchmark value. Statistically meaningful difference was defined as when the facility score fell outside of the confidence interval (± 1.96 standard deviations) for the measure mean (benchmark value). Thus, there are statistically significant differences in performance across facilities for the Breast Screening Recall Rates measure. Facility characteristics among low outlier facilities tend to be rural, small, and non-teaching; whereas high outlier facilities tend to be urban, larger and non-teaching. Feedback received from external stakeholders during a listening session about the Breast Screening Recall Rates measure indicate that a diverse group of stakeholders support its validity. Stakeholders were in agreement that screening mammography and DBT are appropriate imaging modalities that should be used to capture the initial patient population of the measure.
Unintended consequences	Lewin has not identified any unintended consequences related to implementation of the measure.
Which clinical guideline(s)?	The measure is not based on a specific clinical guideline. Expert consensus and evidence in the literature, however, emphasize the importance of appropriate recall (Oregon Health & Science University 2009; American College of Radiology 2013).
Briefly describe the peer reviewed evidence justifying this measure	From the perspective of both clinical quality and efficiency, there are potentially negative consequences if the mammography and DBT recall rate is either too high or too low. A high cumulative dose of low-energy radiation can be a consequence of too many false-positive mammography and DBT recall studies. Radiation received from mammography or DBT may induce more cancers in younger women or those carrying deleterious gene mutations, such as BRCA-1 and BRCA-2. Additional imaging and biopsies after a screening mammography or DBT can also result in over-diagnosis among patients who do not have breast cancer, increasing their anxiety and distress. Alternatively, inappropriately low recall rates may lead to delayed diagnoses or undetected cases of breast cancer (Oregon Health & Science University 2009). Inclusion of DBT when evaluating recall care may improve recall rates and positive prediction values compared to metrics that focus on mammography (Aase et al. [2019]; Aujero et al. [2017]; Bian et al. [2016]; Caumo et al. [2018]; Conant et al. [2016]; Pattacini et al. [2018]; Pozz et al. [2016]; and Skaane [2017]). REFERENCES 1. Oregon Health & Science University. Screening for Breast Cancer: Systematic Evidence Review Update for the U. S. Preventive Services Task Force. Prepared For: Agency for Healthcare Research and Quality U.S. Department of Health and

Human Services. Portland, OR: Oregon Health & Science University, 2009. 2. D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA, et al. ACR BI-RADS® Atlas, Breast Imaging Reporting and Data System. Reston, VA: American College of Radiology, 2013. 3. Aase, H. S., Holen, A. S., Pedersen, K., Houssami, N., Haldorsen, I. S., Sebuodegard, S., Hofvind, S. (2019). A randomized controlled trial of digital breast tomosynthesis versus digital mammography in population-based screening in Bergen: interim analysis of performance indicators from the To-Be trial. 29(3), 1175-1186. doi: 10.1007/s00330-018-5690-x. 4. Aujero, M. P., Gavenonis, S. C., Benjamin, R., Zhang, Z., & Holt, J. S. (2017). Clinical Performance of Synthesized Two-dimensional Mammography Combined with Tomosynthesis in a Large Screening Population. Radiology, 283(1), 70-76. doi: 10.1148/radiol.2017162674. 5. Bian, T., Lin, Q., Cui, C., Li, L., Qi, C., Fei, J., & Su, X. (2016). Digital Breast Tomosynthesis: A New Diagnostic Method for Mass-Like Lesions in Dense Breasts. Breast J, 22(5), 535-540. doi: 10.1111/tbj.12622. 6. Caumo F, Zorzi M, Brunelli S, et al. Digital Breast Tomosynthesis with Synthesized Two-Dimensional Images versus Full-Field Digital Mammography for Population Screening: Outcomes from the Verona Screening Program. Radiology. 2018;287(1):37-46. 7. Conant, E. F., Beaber, E. F., Sprague, B. L., Herschorn, S. D., Weaver, D. L., Onega, T., . . . Barlow, W. E. (2016). Breast cancer screening using tomosynthesis in combination with digital mammography compared to digital mammography alone: a cohort study within the PROSPR consortium. Breast Cancer Res Treat, 156(1), 109-116. doi: 10.1007/s10549-016-3695-1. 8. Pattacini, P., Nitrosi, A., & Giorgi Rossi, P. (2018). Digital Mammography versus Digital Mammography Plus Tomosynthesis for Breast Cancer Screening: The Reggio Emilia Tomosynthesis Randomized Trial. 288(2), 375-385. doi: 10.1148/radiol.2018172119. 9. Pozz, A., Corte, A. D., Lakis, M. A., & Jeong, H. (2016). Digital Breast Tomosynthesis in Addition to Conventional 2DMammography Reduces Recall Rates and is Cost Effective. Asian Pac J Cancer Prev, 17(7), 3521-3526. 10. Skaane, P. (2017). Breast cancer screening with digital breast tomosynthesis. Breast Cancer, 24(1), 32-41. doi: 10.1007/s12282-016-0699-y.

Preliminary Analysis – MUC ID: MUC20-0005 Breast Screening Recall Rates

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This measure addresses the high priority area for Meaningful Measures, "Make Care Affordable" and "Making Care Safer by Reducing Harm Caused in the Delivery of Care". No other Hospital OQR Program or CMS measure addresses breast screening recall, although the Medicare Part C & D Star Ratings Program, Medicare Shared Savings Program, and MIPS each have one related breast cancer screening measure.
Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	The American College of Radiology recommends a recall rate of between 5%-12% (DiPrete et al., 2017) to appropriately follow up on abnormal screenings without the risk of overdiagnosing or causing undue anxiety to patients. MAP should consider if the evidence submitted by the developer includes a clear target recall rate for the accountable entity and patients using the measure to evaluate provider performance since a high or low recall rate could represent a opportunity for improvement. The measure is not based on a specific clinical guideline but is supported by expert clinical consensus and support in the literature.

Does the measure address a quality challenge?	Yes	Breast cancer represents 23% of cancer cases globally (Esserman & Joe, 2019). Recall rate can be used to examine radiologist performance and ensure appropriate cancer detection rates without causing undue anxiety by overdiagnosis and calling back patients for unnecessary tests (DiPrete et al., 2017; Elmore & Lee, 2020) that the developer notes can increase radiation exposure. Mean measure performance is 10.01% [SD 6.3%] with a performance range of 5–12%.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	The Hospital OQR Program does not currently include any measures of breast screening recall rates or measures related to breast cancer screenings. Three other CMS programs have related measures for breast cancer screening, but not specifically for recall rates.
Can the measure be feasibly reported?	Yes	Data elements for this measure are available in claims data for Medicare Fee for Service beneficiaries. The measure is fully specified and the developer notes that the measure has undergone beta testing, reliability testing, and face validity testing. The developer notes that CMS collects Outpatient Imaging Efficiency measures from claims data already and that this measure would use a portion of that data.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Yes	This measure is fully specified and has completed beta testing, reliability testing, and face validity testing at the facility level. The developer notes that reliability scores for the Breast Screening Recall Rates measure ranged from 0.36 to 1.00, with a median reliability score of 0.97. Face validity testing was conducted amongst 32 multistakeholders; 69% of whom strongly agreed or agreed that the measure addresses quality of care. This measure has not been submitted to the NQF endorsement process and final assessment of testing should be completed by the relevant NQF standing committee.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	No	The measure is not currently in use and the developer has not identified any potential negative unintended consequences.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • There was a comment regarding the designation of the target recall rate and the developer reports a range. There was also some concern that this measure is not based on a specific clinical guideline, rather it is based on expert consensus. • From a rural standpoint, there was a comment that this measure focuses more on radiology rather than primary care. Data collection issues: • None Calculation issues: • None Unintended consequences: • No issues identified Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 3.4 1 – 1 vote 2 – 2 votes 3 – 6 votes 4 – 9 votes 5 – 1 vote
Preliminary Analysis Recommendation	Conditional Support for Rulemaking	Conditional support for rulemaking is recommended pending NQF endorsement of the measure.
Summary: What is the potential value to the program measure set?	[redacted]	This measure addresses the Hospital Outpatient Quality Reporting Program high-priority areas, “Making Care Safer” and “Making Care Affordable”. No CMS measure programs include measures of breast screening recall rates. The measure has been fully specified and gone through initial beta testing, reliability testing, and face validity testing.

Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	This claims-based measure identifies recall rates from breast screenings at the facility level. Recall rates adhering to recommended benchmarks (5%-12%) can ensure that abnormal screenings receive appropriate follow-up while avoiding over-diagnosing and causing undue anxiety and testing for patients. MAP should consider if the evidence submitted by the developer includes a clear target recall rate for the accountable entity and patients using the measure to evaluate provider performance since a high or low recall rate could represent a opportunity for improvement. The measure is not based on a specific clinical guideline but is supported by expert clinical consensus and support in the literature. No other CMS measure addresses breast screening recall rates. This measure has not been submitted to NQF for endorsement and is not currently in use. Conditional support for rulemaking is recommended pending NQF endorsement of the measure.

Measure Comments

Author	Submitted Comment
American Medical Association	While this new measure addresses many of the concerns that were identified for OP-9, Mammography Follow-up Rates, the American Medical Association (AMA) believes that reporting recall rates alone provides only a limited assessment of a facility's ability to appropriately screen women for breast cancer. Additional measures would provide a more holistic view, specifically, measures that examine cancer detection rates and positive predictive values for screening and diagnostic exams should be implemented along with this measure. This suite of measures could then provide the comprehensive view on the quality of diagnostic care in this area. As a result, the AMA does not believe that this measure should be implemented until the other measures are available and recommends that the highest level of MAP recommendation be "Conditional Support."
American College of Radiology	The American College of Radiology (ACR) considers MUC20-005 to be a reasonable revision of the previous Mammography Follow-up Rates measure (OP-9). The revision addresses several concerns with OP-9, in particular the inclusion of additional screening imaging modalities and a target recall rate range of 5%-12% recommended by the ACR. It is the only measure related to breast imaging at the hospital level. The ACR recommends conditional support for rulemaking. Using recall rates alone provides only a limited assessment of a facility's ability to appropriately screen women for breast cancer. Additional measures such as cancer detection rate and positive predictive values provide a comprehensive, clinically meaningful basic level audit of a screening mammography program giving the radiologist/radiology department feedback to enable improvement, gives a more accurate picture of the quality of care provided and results in improved patient outcomes. The Mammography Quality Standards Act (MQSA) recommends standard use of this suite of measures by radiology practices. The ACR recommends that CMS consider a means for using this suite of measures in one of its quality programs.
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports efforts to ensure that breast screening recall rates are within acceptable ranges and appreciates that this new measure addresses the concerns identified with the previous measure (OP-9, Mammography Follow-up Rates). The FAH believes that CMS should also explore additional measures to represent a more complete picture of how

	well facilities are in providing timely and appropriate care such as the positive predictive value on screening and diagnostic exams and breast cancer detection rates in women. This set of measures would provide more informative information rather than this measure alone.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Alliance of Dedicated Cancer Centers	We disagree with the Hospital MAP recommendation that this measure be granted conditional support for rulemaking dependent upon NQF endorsement. The foremost concern that the measure's desired acceptable performance range of a 5-12% recall rate is consensus, and not evidence driven. Furthermore, using recall rates alone provides only a limited assessment of a facility's ability to appropriately screen for breast cancer- other measures such as cancer detection rate and positive predictive values more accurately reflect performance. As such, ACR and MQSA recommend the use of a suite of measures by radiology practices. A third concern we have is in the potential differences in patient populations served within a practice, which may result in highly variable recall rates that are not reflective of clinical practice. For example, a practice serving populations at higher risk for cancer, such as tertiary cancer centers, may have increased cancer rates and therefore higher recall rates. Another example of this would be facilities that serve a more transient populations or those with a lower socioeconomic status , will have fewer cases with prior mammograms for comparison, which will increase the recall rate. Another concern expressed by our members was that Breast Screening Recall Rates should not include ultrasound or MRI in the numerator. Our final concern lies in the fact that, as designed, this measure has a desired performance range. Quality measures used in public reporting should be easily understandable for the public – for example higher (or lower) performance indicates higher quality. We applaud the evaluation and consideration of radiology measures in quality reporting programs, and the pursuit of claims-based based measures, but do not support this measure for inclusion in quality reporting programs at this time. We encourage further development and refinement - specifically clarity as to the level of evidence (literature vs. consensus), revisions to the numerator, addressing specific populations, and consideration of a suite of measures to assess quality. Thank you for the opportunity to comment.
RadNet	Radiology has relatively few quality measures and many of those are topped-out. RadNet, therefore, appreciates the development of new quality measures for radiology. However, we have the following concerns regarding the proposed "Breast Screening Recall Rates" measure (MUC20-0005): (1) the proposed 45 day window for follow-up imaging studies is too short and places undue burdens on the capabilities of facilities and staff, (2) recall rates can vary by population according to breast cancer risk factors (e.g., Ashkenazi Jewish communities have higher recall rates), and (3)

	recall rates can vary by screening modality, 2D mammography vs. 3D mammography/digital breast tomosynthesis (DBT), with DBT having lower recall rates than 2D screening mammography.
New York State Radiological Society	Thank you for the opportunity to comment on the proposal to include Breast Screening Recall Rates in the federal Hospital Quality Reporting Program. The NY State Radiological Society and the American College of Radiology Breast Commission are aligned in the below comments regarding inclusion of breast screening recall rates in the Hospital Quality Reporting Program. Using recall rates alone provides only a limited assessment of a facility's ability to appropriately screen women for breast cancer. Additional measures such as cancer detection rate and positive predictive values provide a comprehensive, clinically meaningful basic level audit of a screening mammography program giving the radiologist/radiology department feedback to enable improvement, giving a more accurate picture of the quality of care provided and resulting in improved patient outcomes. The Mammography Quality Standards Act (MQSA) recommends standard use of this suite of measures by radiology practices. The ACR recommends that CMS consider a means for using this suite of measures in one of its quality programs rather than the isolated measure of recall rate. Note: Breast Screening Recall Rates as a measure should not include ultrasound or MRI in the numerator, as it is unusual for MRI to be used in a recall from a screening mammogram. In addition, including breast ultrasound exams and MRIs performed as screening exams for above-average-risk patients (not as a recall from screening) falsely elevates the "recall rate". As the reporting program is based on claims data and there are no CPT codes for screening ultrasound or screening MRI, there would not be a way to separate out the breast MRIs/ultrasounds performed as screening exams from those performed as recalls from screening mammograms and thus the numerator is not reflective of true screening recalls. Many patients qualify and undergo screening breast ultrasound (or MRI) coinciding with annual screening mammography thus within the 45 days following a screening mammogram. Other patients undergo screening breast ultrasound (or MRI) in a staggered schedule alternating every six months with mammography. As such, the 45-day time frame included in the proposal description will falsely impact the screening recall rates. The description does not include a target numerical range for the breast screening recall rate measure. This measure alone can be highly variable due to factors unrelated and not reflective of practice quality. If the upper limit is too low, this will not account for such factors. For example, facilities with a more transient population or population with lower screening rates, such as lower socioeconomic communities, will have fewer cases with prior mammograms for comparison, which will increase the recall rate (recall rate is known to be higher for mammograms without comparisons). Using this measure may therefore accentuate existing health care disparities. Another example would be that some facilities care for populations at higher risk for breast cancer, such as tertiary cancer centers, which increases cancer rates and therefore recall rates to detect those cancers. In conclusion, we support using mammography screening recall rate as part of a quality metric, but only when measured appropriately (no ultrasound or MRI in the numerator, target range that

	allows for variability in practice type) and applied in a meaningful way as part of a comprehensive audit that also includes cancer detection rate and positive predictive value. Sincerely, Donna D'Alessio, MD FACR Chair NY State Radiological Society Breast Imaging Committee References: Honig et al. Factors influencing false positive recall in screening mammography. Acad Radiology 2019; 1-8. https://doi.org/10.1016/j.acra.2019.01.020 Grabler et al. Recall and cancer detection rates in screening mammography: finding the sweet spot. AJR 2017; 208:1–6 DOI:10.2214/AJR.15.15987
Association of American Medical Colleges (AAMC)	The Hospital MAP conditionally supported for rulemaking the breast screening recall rate outcomes measure (MUC2020-0005) pending NQF endorsement. The AAMC agrees that it is critical to ensure that abnormal screenings receive appropriate follow-up. We believe that the NQF-endorsement process will evaluate the appropriateness of this measure's basis on clinical consensus recall rates rather than specific clinical guidelines, in addition to reviewing reliability and validity of the measure. The AAMC agrees with the MAP's recommendation.
American Hospital Association	The AHA disagrees with the MAP's recommendation of Conditional Support and instead suggests the measure receive a recommendation of Do Not Support with Potential for Mitigation. While the measure addresses an important topic, as currently specified it provides incomplete information that may be difficult for patients and providers to use. As NQF's preliminary analysis states, the measure is not based upon clinical practice guidelines for the appropriate level of breast screening recall rates, although such guidelines do exist. As currently specified, the measure would be reported as a percentage; without a benchmark to compare the percentage to, this information is not useful. We urge CMS to consider the history of a similar measure, OP-9, Mammography Follow-up Rates, which was recently removed from the OQR because it no longer aligned with clinical guidelines; this measure also is not based upon current clinical guidelines, so if OP-9 is deficient, so must this measure be. In addition, the purpose of reporting recall rates may be difficult for a consumer looking to choose a provider to understand. While this measure would provide data on whether a provider does unnecessary (or insufficient) scans, it does not provide a complete picture of how accurately a facility detects breast cancer. Thus our recommendation would be for the developer to reconsider this concept in conjunction with other indicators of performance in breast cancer screening, such as positive predictive value.
Federation of American Hospitals	Yes; support for inclusion in the program.
American College of Radiology	The American College of Radiology (ACR) considers MUC20-005 to be a reasonable revision of the previous Mammography Follow-up Rates measure (OP-9). The revision addresses several concerns with OP-9, in particular the inclusion of additional screening imaging modalities and a target recall rate range of 5%-12% recommended by the ACR. It is the only measure related to breast imaging at

the hospital level.

The ACR supports the MAP's recommendation of conditional support for rulemaking. Using recall rates alone provides only a limited assessment of a facility's ability to appropriately screen women for breast cancer. Additional measures such as cancer detection rate and positive predictive values provide a comprehensive, clinically meaningful basic level audit of a screening mammography program giving the radiologist/radiology department feedback to enable improvement, gives a more accurate picture of the quality of care provided and results in improved patient outcomes. The Mammography Quality Standards Act (MQSA) recommends standard use of this suite of measures by radiology practices.

The ACR recommends that CMS consider a means for using this suite of measures in one of its quality programs.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0032
Other Measure Identification Numbers	N/A
Title	Global Malnutrition Composite Score
Program	Hospital Inpatient Quality Reporting Program
Workgroup	MAP Hospital
In what state of development is the measure?	Fully Developed
State of Development Details	Validity Testing. In accordance with CMS requirements, both the individual components and the overall composite have been tested for reliability and validity. The composite measure score and components were tested with a patient sample of 37,450 records from 27 hospitals across 6 states. Minimum patient inclusion criteria was age 65 years and older, length of stay greater than or equal to 24 hours, and admission to malnutrition screening time less than 48 hours from admission. A summary of both validity and reliability testing are included below, but additional details are provided in the appendix section corresponding to this row. Validity testing was completed by constructing a regression model to demonstrate that the predictability of the model significantly improved when the components in aggregate were included into the model over standard predictors of these outcomes such as patient characteristics and primary diagnoses. The findings of the test demonstrated that malnutrition indicators are significantly related to LOS and Readmissions after controlling for the other variables that were included in the model (patient demographics and primary diagnosis) known to be predictive of those outcomes. The R2 statistic for the LOS model was 0.25, and the c-statistic for the 30-day readmissions model was 0.584. When compared to the predictability of other outcome models used for instance in CMS' HCC risk-adjustment models, our model's components were stronger predictors and are comparable to those diagnosis-based models already in place. Reliability Testing. A separate and more recent dataset was constructed to complete additional testing for the composite measure reliability. A total of 179,336 patients age 65 years and older were included in the testing population across 56 acute care hospitals in 10 states. Composite measure reliability was assessed using the variance components—extracted from a linear mixed effects (LME) model—to calculate the intraclass correlation coefficient (ICC). The LME framework was employed, because it accommodates inclusion of both fixed and random effects, the latter of which account, statistically, for the correlated or non-independent nature of measures that are hierarchically nested within health systems (N = 10) and practice sites (N = 56). The model variance ($\sigma 2$) can then be partitioned into components that are, in turn, used to calculate the Cowitch case minimums applied, the result was an ICC of 0.839 which reflects an acceptable level of reliability and ability to detect meaningful differences among provider groups. Additional testing information is provided in the attachment: Global Malnutrition Composite Measure_Testing Attachment.
Measure Description	Composite measure consisting of 4 component measures of optimal malnutrition care focuses on adults 65 years and older admitted to inpatient service who received care appropriate to their level of malnutrition risk and/or malnutrition diagnosis if identified. Appropriate care for inpatients includes to malnutrition risk screening, nutrition assessment for that at-risk, and proper malnutrition severity indicated along with a corresponding nutrition care plan that recommends treatment approach.
Numerator	The Global Malnutrition Composite Score is comprised of four component measures which are scored separately and whose population is sourced from the overall composite measure denominator. 1. Screening for malnutrition risk at admission. 2. Completion of a nutrition assessment for patients who screened for risk of malnutrition. 3. Appropriate

	documentation of malnutrition diagnosis for patients identified with malnutrition. 4. Development of a nutrition care plan for malnourished patients. The composite measure score is calculated by summing and then averaging the performance scores for each of the four component measures included in the overall composite measure. Each component measure is a proportion measure.
Denominator	The measure population from which the composite's component measures are sourced from are patients age 65 years and older who are admitted to an acute inpatient hospital.
Exclusions	1. All Four Component Measures: patients with a length of stay less than 24 hours; 2. Component Measure #1 only: admission to screening time interval greater than 48 hours; 3. Component Measure #3 and #4 only: discharge status of hospice or left against medical advice.
Measure type	Composite
What is the NQF status of the measure?	Submitted
NQF ID number	3592
Year of next anticipated NQF CDP endorsement review	2020
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as endorsed by NQF?	N/A
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	EHR
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	Facility
In which setting was this measure tested?	Hospital inpatient acute care facility
What NQS priority applies to this measure?	N/A

What one primary meaningful measure area applies to this measure?	Admissions and readmissions to hospitals
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote effective communication and coordination of care
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Other, Nutrition
What is the target population of the measure?	All adult inpatients age 65 years and older regardless of payer in need of malnutrition screening, nutrition assessment if found at-risk of malnutrition, or a malnutrition diagnosis and care plan if found malnourished by assessment.
Is this measure an eCQM?	Yes
If eCQM, enter Measure Authoring Tool (MAT) number	986
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	Yes
Comments	Per submitter e-mail 7/8/2020: "We will be submitting Bonnie Testing Attachment shortly as we are working with CMS's technical contractor in the JIRA to complete the last step of the Bonnie testing."
Measure steward	Academy of Nutrition and Dietetics
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Sharon McCauley; 312-899-4823; smccauley@eatright.org
Primary Submitter Contact Information	Angel Valladares; 202-446-2242; avalladares@avalere.com
Long-Term Measure	N/A

Steward Contact Information	
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A

Evidence that the measure can be operationalized	Three published studies describe implementation of the component measures of this composite measure. One study outlined the usability and feasibility of the composite measure components (Doley, 2018). A second published study reported on the testing of the composite's component measures and how the testing site used the testing results to implement improvements to hospital workflow (Nepple, 2019). Another study published the measure performance across a learning collaborative of US hospitals as well as how the measures were used to assess quality improvement (Valladares, 2020). REFERENCES: Doley J, Phillips W, Talaber J and Leger-LeBlanc G. Early Implementation of Malnutrition Clinical Quality Metrics to Identify Institutional Performance Improvement Needs. Journal of the Academy of Nutrition and Dietetics. 2018; Article in Press. doi.org/10.1016/j.jand.2018.02.020. Nepple K, Tobert C, Valladares A, Mitchell K, Yadrick M. Enhancing identification and management of hospitalized patients who are malnourished: a pilot evaluation of electronic quality improvement measures. J Acad Nutr Diet. 2019;119(9S2):S32-S39. Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, Mccauley S. How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative. JPEN J Parenter Enteral Nutr. 2020.
How is the measure expected to be reported to the program?	eCQM
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	A bootstrap resampling methodology was employed to generate a 95% confidence interval around the composite score mean. The 95% confidence interval will then be used to group providers into performance categories (Low, Medium, High).Participating hospitals were categorized into three tiers that reflect those whose composite measure performance

	scores were above, overlapped with, or were below the 95% estimate generated in the bootstrap analysis. If a hospital's composite score was assigned a Tier 3 score it was above the estimated confidence interval and implies that the specific hospital's performance was above the average of the estimate developed from the aggregate of all reporting sites. A hospital receiving a Tier 2 score means their performance was not meaningfully different than the estimated mean. Finally, a hospital receiving a Tier 1 score implies that their composite performance score fell below the mean estimate interval reflective of lower than expected performance. Among hospitals that meet the case minimum of 20 patients and at least 3 reportable measures, 44.7% of hospitals were in the highest performing Tier 3, 14.9% were in Tier 2, and 40.4% were in Tier 1.January 1, 2019 through December 31, 2019 [Table]Category = Tier 3, All Participants Number of Hospitals = 22, 39.3%, Participants N greater than or equal to 20 Number of Hospitals = 21, 44.7%Category = Tier 2, All Participants Number of Hospitals = 3, 5.4%, Participants N greater than or equal to 20 Number of Hospitals = 7, 14.9%Category = Tier 1, All Participants Number of Hospitals = 31, 55.3%, Participants N greater than or equal to 20 Number of Hospitals = 19, 40.4%This tiering approach informed by the bootstrap sample derived from the observed performance measures was used to appropriately distinguish sites with varying degrees of performance among the component measures. These differences ultimately translated to variation in performance on the overall composite measure. Our specific sample of sites is relatively homogeneous because the participating hospitals have been targeting improvement on these quality measures for 1-3 years.
Unintended consequences	No unintended consequences have been reported by participating hospitals over 3 years of performance reporting.
Which clinical guideline(s)?	The components of this composite measure are supported by multiple clinical guidelines that recommend the following: (1) malnutrition screening for patients admitted into the acute inpatient care setting; (2) nutrition assessment for patients at-risk of malnutrition in order to form the basis for an appropriate nutrition intervention; (3) appropriate recognition, diagnosis, and documentation of the nutrition status of a patient in order to address their condition with an appropriate plan of care and communicate patient needs to other care providers. By completing a malnutrition screening early during the patient's admission, patients at-risk of malnutrition are identified earlier and can be referred to a dietitian to complete a nutrition assessment. A completed nutrition assessment for patients at-risk of malnutrition (typically first identified by malnutrition screening around admission time) facilitates subsequent development of a nutrition care plan that includes appropriate interventions to address the patient's malnutrition. The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) recommends the following: 1. Screening for nutrition risk is suggested for hospitalized patients (Evidence Grade E); 2. Nutrition assessment is suggested for all patients who are identified to be at nutrition risk by nutrition screening (Evidence Grade E); 3. Nutrition support intervention is recommended for patients identified by screening and assessment as at risk for malnutrition or malnourished. (Grade Evidence C). REFERENCES: Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24. The British Association for Parenteral and Enteral Nutrition recommends the maintenance of documentation for all individuals including results of nutritional screening and assessments (which include malnutrition findings), along with consequent action plans and treatment goals. If the patient is transferred to another care setting, this information should be readily available to all new caregivers to ensure continuity of care. British Association for Parenteral and Enteral Nutrition. Malnutrition Matters, A Toolkit for Clinical Commissioning Groups and providers in England. Published 2012. Retrieved from: http://www.bapen.org.uk/pdfs/bapen_pubs/bapen-toolkit-for-commissioners-and-providers.pdf. A consensus statement from the Academy of Nutrition and Dietetics states that the registered dietitian's (RD's) assessment of critically ill adults should include, but not be limited to, the following: Food and Nutrition-Related History,

	Anthropometric Measurements, Biochemical Data, Medical Tests and Procedures, Nutrition-Focused Physical Findings, Client History. Assessment of the above factors is needed to correctly diagnose nutrition problems and plan nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes. Academy of Nutrition and Dietetics. CI: Nutrition Assessment of Critically Ill Adults 2012. Academy of Nutrition & Dietetics Evidence Analysis Library. Published 2012. Retrieved from: http://www.andeal.org/topic.cfm?menu=4800.
Briefly describe the peer reviewed evidence justifying this measure	Nationwide analysis of hospitalizations with malnutrition diagnoses concluded that 8% of all non-neonatal and non-maternal adult hospitalizations were coded for a diagnosis of malnutrition. Furthermore, malnourished patients experienced up to 5x risk of in-hospital mortality, up to 2x higher hospital costs, up to 2x longer length of stay, and 55% higher readmissions than discharges without malnutrition. (Barrett, 2018). Recently published research suggests that adopting malnutrition standards of care is a feasible and valuable endeavor for hospitals to undertake. Multiple studies have shown that optimal malnutrition care quality improvement programs improve care coordination between clinical disciplines responsible for nutrition care and that those improvements are associated with outcomes (Valladares, 2020; Danis, 2019; Nepple, 2019; Sriram, 2018). A cost evaluation was conducted on one of the quality improvement programs, savings in terms of avoided hospital readmissions and reduced patient length of stay for patients in the quality improvement program totaled up to $4.8 million (Sulo, 2017). Clinical evidence and best practices support the need for quality measures that incentivize early identification, diagnosis, intervention, and effective transitions of care for hospitalized patients who are at-risk or malnourished (McCauley, 2019). Malnutrition risk identified in patients through a malnutrition screening was able to predict certain patient outcomes including length of stay, mortality, and post-operative complications. (Sauer, 2019; Silver, 2018; Allard, 2016; Khalatbari-Soltani, 2016; Kruizenga, 2016; Agarwal, 2013). A large national study understanding inpatient data from US hospitals, demonstrated that as many as 1 in 3 hospitalized patients are at-risk of malnutrition according to validated screening (Sauer, 2019). The peer reviewed evidence cited for this measure also supports the assessment of patients at-risk of malnutrition via the completion of a nutrition assessment that can confirm malnutrition and initiate a care plan recommending appropriate interventions (Hudson, 2018). Multiple studies have reported patient outcomes associated with malnutrition when identified by nutrition assessment, was independently associated with higher hospital mortality, higher incidence of infection, and an increased risk of readmission (Hiller, 2017; Lew, 2016). Additionally, a recently published study demonstrated that malnourished patients were older (61 vs 58 years, P < .0001), had longer LOS (15 vs 12 days, P = .0067) and were more likely to be readmitted within 30 days (40% vs 23%, P < .0001). In adjusted models, 30-day readmissions (odds ratio [OR] 2.13, 95% confidence interval [CI] 1.82-2.48) and hospital mortality (OR 1.47, 95% CI 1.0-1.99) were increased in those who had >2-day stay (Hudson, 2018). Two research studies associated early nutritional care after risk identification with improved outcomes such as reduced length of stay, reduction in risk of readmissions, and cost of care (Lew, 2016), (Meehan, 2016). An additional study of a learning collaborative of US hospitals demonstrated a statistically significant lower risk of 30-day readmission for malnourished patients who had a documented nutrition care plan (Valladares, 2020). Nutritional status and progress are often not adequately documented in the medical record. It can be difficult to tell when (or if) patients are consuming food and supplements. In addition, nutritional procedures and EHR-triggered care are often lacking in the hospital. Similarly, nutritional care plans and patient issues are poorly communicated to post-acute facilities and PCPs (Corkins, 2014). Additionally, room to improve coordination between registered dietitians and physicians has also been reported (Chambers, 2019; Vest, 2018). Finally, documentation of malnutrition diagnoses has been associated with significant healthcare cost savings per hospital day per patient (Amaral, 2007). REFERENCES: Agarwal E, Ferguson M, Banks M, et al. Malnutrition and poor food intake are associated with prolonged hospital stay, frequent readmissions, and greater in-

hospital mortality: results from the Nutrition Care Day Survey 2010. Clinical nutrition (Edinburgh, Scotland). 2013;32(5):737-745. Allard JP, Keller H, Teterina A, et al. Lower handgrip strength at discharge from acute care hospitals is associated with 30-day readmission: A prospective cohort study. Clinical nutrition (Edinburgh, Scotland). 2016;35(6):1535-1542. Amaral TF, Matos LC, Tavares MM, Subtil A, Martins R, Nazaré M, et al. The economic impact of disease-related malnutrition at hospital admission. Clin Nutr. 2007 Dec;26(6):778–84. Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. ONLINE. August 30, 2018. U.S. Agency for Healthcare Research and Quality. Available: www.hcupus.ahrq.gov/reports.jsp. Chambers R, Bryan J, Jannat-khah D, Russo E, Merriman L, Gupta R. Evaluating Gaps in Care of Malnourished Patients on General Medicine Floors in an Acute Care Setting. Nutr Clin Pract. 2019;34(2):313-318. Corkins MR, Guenter P, Dimaria-ghalili RA, et al. Malnutrition diagnoses in hospitalized patients: United States, 2010. J Parenter Enteral Nutr. 2014;38(2):186-95. Danis K, Kline M, Munson M, et al. Identifying and Managing Malnourished Hospitalized Patients Utilizing the Malnutrition Quality Improvement Initiative: The UPMC Experience. J Acad Nutr Diet. 2019;119(9 Suppl 2):S40-S43. Hiller LD, Shaw RF, Fabri PJ. Difference in Composite End Point of Readmission and Death Between Malnourished and Nonmalnourished Veterans Assessed Using Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Clinical Characteristics. JPEN J Parenter Enteral Nutr. 2017;41(8):1316-1324. Hudson L, Chittams J, Griffith C, Compher C. Malnutrition Identified by Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Is Associated With More 30-Day Readmissions, Greater Hospital Mortality, and Longer Hospital Stays: A Retrospective Analysis of Nutrition Assessment Data in a Major Medical Center. JPEN J Parenter Enteral Nutr. 2018. Khalatbari-Soltani S, Marques-Vidal P. Impact of nutritional risk screening in hospitalized patients on management, outcome and costs: A retrospective study. Clinical nutrition (Edinburgh, Scotland). 2016;35(6):1340-1346. Kruizenga H, van Keeken S, Weijs P, et al. Undernutrition screening survey in 564,063 patients: patients with a positive undernutrition screening score stay in hospital 1.4 d longer. The American journal of clinical nutrition. 2016;103(4):1026-1032. Lew CC, Yandell R, Fraser RJ, Chua AP, Chong MF, Miller M. Association Between Malnutrition and Clinical Outcomes in the Intensive Care Unit: A Systematic Review. JPEN. Journal of parenteral and enteral nutrition. 2016. McCauley SM, Mitchell K & Heap A. The Malnutrition Quality Improvement Initiative: A Multiyear Partnership Transforms Care. J Acad Nutr Diet. 2009;119(9 Suppl 2):S18-S24. Meehan A, Loose C, Bell J, Partridge J, Nelson J, Goates S. Health System Quality Improvement: Impact of Prompt Nutrition Care on Patient Outcomes and Health Care Costs. J Nurs Care Qual. 2016. Nepple K, Tobert C, Valladares A, Mitchell K, Yadrick M. Enhancing identification and management of hospitalized patients who are malnourished: a pilot evaluation of electronic quality improvement measures. J Acad Nutr Diet. 2019;119(9S2):S32-S39. Sauer AC, Goates S, Malone A, et al. Prevalence of Malnutrition Risk and the Impact of Nutrition Risk on Hospital Outcomes: Results From nutrition Day in the U.S. JPEN J Parenter Enteral Nutr. 2019;43(7):918-926. Silver HJ, Pratt KJ, Bruno M, Lynch J, Mitchell K, Mccauley SM. Effectiveness of the Malnutrition Quality Improvement Initiative on Practitioner Malnutrition Knowledge and Screening, Diagnosis, and Timeliness of Malnutrition-Related Care Provided to Older Adults Admitted to a Tertiary Care Facility: A Pilot Study. J Acad Nutr Diet. 2018;118(1):101-109. Sriram K, Sulo S, Vanderbosch G, et al. Nutrition-Focused Quality Improvement Program Results in Significant Readmission and Length of Stay Reductions for Malnourished Surgical Patients. JPEN J Parenter Enteral Nutr. 2018;42(6):1093-1098. Sulo S, Feldstein J, Partridge J, Schwander B, Sriram K, Summerfelt WT. Budget Impact of a Comprehensive Nutrition-Focused Quality Improvement Program for Malnourished Hospitalized Patients. Am Health Drug Benefits. 2017;10(5):262-270. Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, Mccauley S. How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative.

JPEN J Parenter Enteral Nutr. 2020. Vest MT, Papas MA, Shapero M, Mcgraw P, Capizzi A, Jurkovitz C. Characteristics and Outcomes of Adult Inpatients With Malnutrition. JPEN J Parenter Enteral Nutr. 2018;42(6):1009-1016.

Preliminary Analysis – MUC ID: MUC20-0032 Global Malnutrition Composite Score

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This composite measure addresses an important clinical topic not currently addressed by the measures in the Hospital Inpatient Quality Reporting Program (Hospital IQR Program) set, as research (Sauer AC, et al., 2019) has found approximately 1 in 3 hospitalized patients at risk for malnutrition. The developer suggests that implementation of this measure may lead to improvement in outcomes, such as reductions in 30-day readmissions, associated costs, and resource utilization. This measure may be considered to address the high priority Meaningful Measure area to "Promote Effective Communication and Coordination of Care" through the EHR data source and as an eCQM.
Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	Yes	This is a composite measure that consists of four measures of malnutrition focused on patients 65 years and older: 1. Screening for malnutrition risk at admission. 2. Completion of a nutrition assessment for patients who screened for risk of malnutrition. 3. Appropriate documentation of malnutrition diagnosis for patients identified with malnutrition. 4. Development of a nutrition care plan for malnourished patients. The developer cites (Valladares, et al., 2020) that patients 65 years and older with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day hospital readmissions compared to those without a care plan. Additionally this research showed Length of Stay (LOS) to be on average 3 days longer for malnourished patients without a nutrition care plan. However, evidence submitted to the Fall 2020 NQF endorsement process by the measure developer notes that screening for malnutrition risk or conducting nutrition assessments were rated Grade E or supported by level IV or V evidence. Additionally, the evidence for providing a nutrition support intervention for patients identified by screening and assessment at risk for malnutrition or malnourished was rated Grade C or supported by at least one level III investigation. MAP should consider if the evidence submitted supports inclusion of the measure in the Hospital Inpatient Quality Reporting Program.

Does the measure address a quality challenge?	Yes	Research has shown malnourished patients experience increased risk of in-hospital mortality, higher hospital costs, longer length of stay, and higher likelihood of readmission (Barrett, et al., 2018). It should also be noted that as this measure focuses on patients ages 65 and older, that a recently published study has shown malnourished paients to be older, had a longer length of stay, and were more likely to be readmitted within 30 days (Hudson, et cal., 2018). The developer notes that among hospitals that meet the case minimum of 20 patients and at least 3 reportable measures in 2019, 44.7% of hospitals were in the highest performing Tier 3, 14.9% were in Tier 2, and 40.4% were in Tier 1. This range in performance demonstrates opportunities for improvement.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	The Hospital Inpatient Quality Reporting Program (Hospital IQR Program) does not currently include any measures with similar areas of clinical focus or target population.
Can the measure be feasibly reported?	Yes	All components and required data elements within this composite measure are captured within an electronic health record and can be feasibly reported. The required data elements are routinely generated and used during care delivery, as the first component of this composite measure is screening for malnutrition risk at admission. Capturing of the required data can be implemented as has been shown by hospitals that have already put these measure components into operational use.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Yes	The measure is specified and tested at the hospital inpatient acute care facility level of analysis. The Scientific Methods Panel voted in October 2020 to pass this measure on the scientific acceptability of the methodological approach to testing. NQF's first evaluation of this measure to be considered for endorsement will occur in 2020-2021, as this measure is be evaluated as part of the Fall 2020 cycle.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	No	Per the measure developer, no unintended consequences have been reported by participating hospitals over 3 years of performance reporting.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • This is an important area of measurement and an important issue for the rural setting. It seems achievable in the rural setting with rural hospitals. Data collection issues: • No issues identified. There was a comment that having an electronic version would be easier for data collection. Calculation issues: • There was some concern with case volume within the rural setting. Unintended consequences: • No issues identified Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 3.8 1 – 0 vote 2 – 1 vote 3 – 2 votes 4 – 14 votes 5 – 1 vote
Preliminary Analysis Recommendation	Conditional Support for Rulemaking	Conditional support for rulemaking is recommended pending NQF endorsement.
Summary: What is the potential value to the program measure set?	[redacted]	This measure addresses a clinical topic area not currently addressed by the measures in the Hospital Inpatient Quality Reporting Program (Hospital IQR Program) set. Furthermore, this measure may be considered to address the high priority Meaningful Measure area to "Promote Effective Communication and Coordination of Care" through the EHR data source and as an eCQM. MAP should consider if the evidence submitted supports inclusion of the measure in the Hospital Inpatient Quality Reporting Program. The measure was voted on and passed by the Scientific Methods Panel in October 2020 and will be evaluated for endorsement for the first time as part of the Fall 2020 cycle.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	This measure encourages the identification and treatment of malnutrition upon hospital admission for adults age 65 years and older, leading to reduced risk of 30-day readmission, shortened length of stay, reduced risk of in-patient mortality, and lower hospital costs, as compared to malnourished patients that are not screened for risk and treated appropriately. This is a prevalent clinical issue, as recent research has found approximately 1 in 3 hospitalized patients at risk for malnutrition (Sauer AC, et al., 2019). Conditional support for rulemaking is recommended pending NQF endorsement of the measure.

Measure Comments

Author	Submitted Comment
American Society for Parenteral and Enteral Nutrition	On behalf of the American Society for Parenteral and Enteral Nutrition (ASPEN), we appreciate the opportunity to submit comments in support of NQF #3092, the Global Malnutrition Composite Score. As multi-disciplinary clinicians and researchers, we have been advocating for identification, prevention, and treatment of hospital-based malnutrition since the inception of our organization in 1976. ASPEN is dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism. ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With more than 6,000 members from around the world, ASPEN is a community of dietitians, nurses, pharmacists, physicians, scientists, students, and other health professionals from every facet of nutrition support clinical practice, research, and education. We have significant experience and understanding of the processes of care for identification and treatment that are outlined and recommended in the malnutrition composite score. In 2012, ASPEN initiated Malnutrition Awareness Week™, a week of education and intervention, which in 2020 included 115 national and international organizations which potentially reached over 1 million clinicians and nutrition professionals. As part of this effort, the US Senate has approved Senate Resolution 716: (1) which designates the week of October 5 through October 9, 2020, as ``Malnutrition Awareness Week™''; (2) recognizes registered dietitian nutritionists and other nutrition professionals, health care providers, social workers, advocates, caregivers, and other professionals and agencies for their efforts to advance awareness, treatment, and prevention of malnutrition; (3)(A) recognizes the importance of existing Federal nutrition programs for their role in combating malnutrition; and (B) supports emergency funding for those critical Federal nutrition programs for the duration of the Coronavirus Disease 2019 (COVID-19) pandemic. ASPEN has also developed a widely used nutrition care pathway to help guide processes from hospital admission to discharge. ASPEN has been involved in many quality and research efforts bringing forth improvements in malnutrition care, impact of better care for hospitalized and critical care patients, and documentation of these diagnoses. These include: • Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition) 2012 • Feasibility of accessing data in hospitalized patients to support diagnosis of malnutrition by the Academy-A.S.P.E.N. malnutrition consensus recommended clinical characteristics 2013 • Critical Role of Nutrition in Improving Quality of Care: An Interdisciplinary Call to Action to Address Adult Hospital Malnutrition 2013 • Nutrition Screening and Assessment in Hospitalized Patients: A Survey of Current Practice in the United States 2014 • Addressing Disease-Related Malnutrition in Hospitalized Patients: A Call for a National Goal 2015 • Malnutrition identified by Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition is associated with more 30-day readmissions, greater hospital mortality, and longer hospital stays: a retrospective analysis of nutrition assessment data in a major medical center. 2018 • Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition consensus malnutrition characteristics: usability and association with outcomes 2019

ASPEN also partnered with the Agency for Healthcare Research and Quality to develop data briefs on malnutrition in hospitalized patients and impact on hospital readmissions. This work has helped quantify the issue on a national level and helped us measure the growth of diagnosed malnutrition in this population. ASPEN is involved with a current AHRQ Technical Advisory Panel continuing to look at these issues. These reports clearly demonstrate higher costs and increased readmissions in those patients identified with malnutrition.

• Non-Maternal and Non-Neonatal Inpatient Stays in the United States Involving Malnutrition, 2016 (PDF)

• Characteristics of Hospital Stays Involving Malnutrition, 2013 (PDF , HTML)

• All-Cause Readmissions Following Hospital Stays for Patients With Malnutrition, 2013 (PDF , HTML)

ASPEN's efforts in reporting on the impact of malnutrition and the importance of proper identification and treatment of malnutrition demonstrate how critical it is that hospitals focus on this condition. The steps in the process of detecting, diagnosing, documenting, care planning, preventing, and treating malnutrition need to be measured in hospitalized patients. This global composite measure as outlined in NQF # 3092 provides an opportunity to standardize processes of care and data collection to track and monitor quality of care for malnourished hospitalized patients and would be a critical addition to existing measures that hospitals currently focus on. ASPEN highly supports passage of this composite measure.

Defeat Malnutrition Today

Defeat Malnutrition Today, a coalition of over 100 national, state and local organizations dedicated to ending older adult malnutrition, appreciates the opportunity to offer comments to NQF.

We strongly support MUC 20-0032, the Global Malnutrition Composite Score, and urge its inclusion in the IQR. This issue takes on great urgency due to the COVID-19 pandemic. Studies show that undiagnosed and untreated malnutrition may be intensifying the COVID-19 crisis, thus increasing the importance of endorsing this measure now. Early in the pandemic, a potentially higher prevalence of malnutrition among older patients admitted to the hospital with COVID-19 was identified; Li et al in Wuhan, China, documented that 52.7 percent of older adults with COVID-19 were malnourished and 27.5 percent were at risk of malnutrition (2020). Further, nutrition status has been identified as an important factor influencing the outcome of COVID-19 patients (Laviano et al, 2020).

In general, malnutrition affects approximately 20 percent to 50 percent of admitted hospital patients in the US. (Barker et al, 2011). Malnourished patients are more likely to develop a healthcare-acquired condition such as pressure ulcers. They are also more likely to have delayed wound healing, decreased respiratory and cardiac function, muscle wasting, and functional loss, in turn increasing their risk of falls, longer length of hospital stays, higher readmission rates, and higher treatment costs. In short, diagnosing and treating malnutrition leads to better patient outcomes and lowered healthcare costs.

Adoption of the Global Malnutrition Composite Score by the IQR has the potential to offset these negative impacts of malnutrition through quick screening, identification, diagnosis and treatment. NQF should endorse this measure.

References

Barker, L. A., Gout, B. S., Crowe, T. C. (2011). Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. International Journal of Environmental Research and Public Health, 8(2), 514-527.

Laviano, A., Koverech, A., Zanetti, M. (2020). Nutrition support in the time of SARS-CoV-2 (COVID-

19). Journal of Nutrition, 74, 1108-34.

Li, T., Zhang, Y., Gong, C., Wang, J., Liu, B., Shi, L., Duan, J. (2020). Prevalence of malnutrition and analysis of related factors in elderly patients with COVID-19 in Wuhan, China. European Journal of Clinical Nutrition, 74, 871-875. https://doi.org/1038/s41430-020-0642-3

Academy of Nutrition and Dietetics

Data informed decisions can identify and inform staff to prioritize those with malnutrition risk for early nutrition intervention. The publicly available Malnutrition Quality Improvement Initiative (MQii) Toolkit provides practical, interdisciplinary tools and resources to help hospitals implement malnutrition best practices and adopt eCQMs to measure their success in meeting the standards of care. The MQii Toolkit is customizable for individual hospitals and enables the implementation of local QI projects tailored to the unique needs and availability of resources at individual institutions. Use of the MQii Toolkit ensures the adoption of standardized best practice recommendations through the provision of a single, easy to-reference resource. The Toolkit is organized into 10 navigable sections with a complete section dedicated to planning for data collection reducing the burden of data collection and reporting. Additionally, included is a clinical workflow template delineating the steps that should be taken to assess and address malnutrition in patients, along with timeframes for implementing each step.1,2

1Fitall, Eleanor, Jones Pratt, Kelsey, McCauley, Sharon M, Astrauskas, Giedre, Heck, Tracey, Hernandez, Beverly, Johnston, Jill, Silver, Heidi J, Mitchell, Kristi. Improving Malnutrition in Hospitalized Older Adults: The Development, Optimization, and Use of a Supportive Toolkit. Journal of the Academy of Nutrition and Dietetics, Volume 119, Issue 9, S25 - S31. September 2019. https://jandonline.org/article/S2212-2672(19)30503-9/pdf

2Wills, Jennifer. Prioritizing Malnutrition Care Through Discrete eCQM Data Tracking in the Electronic Health Record for an Academic Medical Center. Journal of the Academy of Nutrition and Dietetics, Volume 119, Issue 9, S63, September 2019. https://jandonline.org/article/S2212-2672(19)30584-2/pdf

Malnutrition, defined as a nutrition imbalance including under-nutrition and over-nutrition, is a pervasive, but often under-diagnosed, condition in the United States. Malnutrition prevalence is exacerbated among patients who are already ill: chronic diseases such as diabetes, cancer, and gastrointestinal, pulmonary, heart, and chronic kidney disease. Chronic disease treatments can result in changes in nutrient intake and ability to use nutrients, which can lead to malnutrition. The Global Malnutrition Composite Score quality measure is vital to implementation of malnutrition quality improvement and advancing and standardizing nutrition care in hospitalized patients. Lack of evaluation and management can result in negative health and financial outcomes as malnourished adults have been found to utilize more health services with more visits to physicians, hospitals, and emergency rooms. Nutrition interventions have been repeatedly shown to positively impact health status and cost-effective in improving health outcomes among malnourished patients.

The Global Malnutrition Composite Score quality measure within the Malnutrition Quality Improvement Initiative (MQii) works to help hospitals and health systems improve malnutrition care and achieve better outcomes. Drawing on the reported experiences of RDNs in MQii Learning Collaborative hospitals and other clinicians it is possible to identify potential hospital practice changes and opportunities for healthcare delivery systems to help promote and better prepare for delivering quality malnutrition care to COVID-19 patients.1 With the SARS-CoV-2 virus triggering the COVID-19 pandemic, the risk for malnutrition and its impacts may be even more pronounced. The Global Malnutrition Composite Score quality measure supports acceleration and dissemination of malnutrition care best practices and thus provides an opportunity to examine how COVID-19 has changed malnutrition identification and care of hospitalized patients. Implications for hospital

	practice changes in malnutrition care included the need for an interdisciplinary approach, active patient and family engagement, early nutrition intervention protocols, flexibility in accomplishing nutrition goals, and leveraging health information technology. 1 Arensberg, Mary Beth, Brunton, Cory, Everett, Wendy, McCauley Sharon M. Feedback from the Frontline and Best Practices: The Challenges and Impact of COVID-19 on Malnutrition Care in Hospitalized Patients. Journal of Nutrition and Diet Supplements, Volume 4, Issue 1, 101, June 2020. http://www.scienceinquest.com/open-access/pdf/jnds/feedback-from-the-frontline-and-best-practices-the-challenges-and-impact-of-covid-19-on-malnutrition-care-in-hospitalized-patients.php
American Medical Association	The AMA appreciates that the developer has been responsive to the MAP's previous request to combine these measures into a composite. During the previous MAP review, the MAP did not support the inclusion of appropriate documentation of a malnutrition diagnosis since it did not receive endorsement and because it was a documentation measure and the remaining measures received the "Refine and Resubmit" recommendation. In addition, none of these measures achieved NQF endorsement due to concerns with the evidence, burden of several of the requirements (e.g., documenting within 24 hours of admission, all the components required in the plan of care), and lack of exclusions. The AMA requests that the MAP recommendation be "Conditional Support" with the conditions of NQF endorsement and review and confirmation that these concerns were adequately addressed.
Healthcare Nutrition Council	National Quality Forum 1099 14th Street, NW Suite 500 Washington, DC 20005 January 6, 2021 Re: MAP MUC 2020 Comment Period – MUC20-0032 – "Global Malnutrition Composite Score" To Whom It May Concern, The Healthcare Nutrition Council (HNC) appreciates the opportunity to submit comments in response to the Measure Under Consideration (MUC) MUC20-0032 "Global Malnutrition Composite Score" for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program. HNC is an association representing manufacturers of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), parenteral nutrition (PN) formulas, supplies and equipment. Our mission is to improve health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. Our organization aims to promote nutritional screening, diagnosis, assessment, appropriate and timely clinical nutrition interventions, as well as patient access to specialized nutrition support products and services throughout the continuum of care. HNC is pleased to see NQF considering inclusion of the Global Malnutrition Composite Score (MUC20-0032) in the Hospital IQR Program. As NQF is aware, malnutrition is widely recognized as having a significant role in health outcomes and healthcare costs. Addressing malnutrition is essential to improving quality of care and outcomes for patients. To just name a few important considerations, malnutrition has been shown to lead to increased complications, longer hospitalizations and more readmissions for patients being treated in facility settings. In addition, malnutrition is a risk factor for other adverse clinical events, such as falls, and is also tied to higher rates of stroke, heart failure, cancer, and COPD. For these reasons, it's important that CMS and others include robust nutrition measures in its

	quality reporting programs, including and especially the IQR Program, which tracks care for acutely ill, hospitalized patients. HNC therefore offers its strong support for the addition of the Global Malnutrition Composite Score in the IQR program. HNC also encourages NQF to continue advancing other nutritional-related measures for inclusion in CMS and other quality programs, and we stand ready to work with NQF and other stakeholders with this important work. HNC thanks NQF for allowing us the opportunity to provide feedback on the inclusion of these measures. Should you wish to discuss these comments further, please contact Berit Dockter at bdockter@healthcarenutrition.org. Sincerely, Robert Rankin Executive Director
Premier	Premier supports this measure, but recommends that CMS not move forward until it has received endorsement. The measure is reflective of current best practices and is an important area to track quality of care.
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) appreciates that the measure developer was responsive to previous MAP recommendations on the individual nutrition measures. While three of the components received a recommendation to refine and resubmit once a composite was developed, the MAP did not support including the documentation of a malnutrition diagnosis because it is just a documentation measure. This measure was also not endorsed due to the lack of evidence to support that documentation of a diagnosis was directly linked to improving patient outcomes. In addition the other three measures did not achieve NQF endorsement due to concerns with the underlying evidence, burden of several of the requirements (e.g., documenting within 24 hours of admission, all the components required in the plan of care), and lack of exclusions. The FAH believes that the composite should be endorsed by NQF prior to implementation in the Hospital Inpatient Quality Reporting Program to ensure that these concerns were adequately addressed. As a result, the FAH requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Avalere Health	I appreciate the opportunity to submit my comments in support of NQF #3092, the Global Malnutrition Composite Score. As a clinical nutrition leader at a world-class academic medical center and health system, I have direct experience with implementing the processes of care that are outlined and recommended in the malnutrition composite score. Our work at UPMC to enhance our malnutrition recognition program with Nutrition focused physical assessment (NFPA) has elevated the focus of malnutrition care across our health system.

Increased multidisciplinary collaboration, especially between providers and the clinical nutrition team, in identification and treatment of malnutrition has also been recognized.

As outlined in a peer-reviewed research article published in 2019[1], we specifically tackled improvements in quality of care guided by the malnutrition care process that is addressed by the component measures in the composite with support from the Malnutrition Quality Improvement Initiative (MQii) resources and team. We were able to improve all components of the Global Malnutrition Composite Score with improved timeliness of screening and nutrition assessment. In addition, there was improved care coordination between RNDs and MDs.to ensure patients are properly diagnosed with malnutrition and referred to treatment.

As a result of the hospital-wide efforts to improve risk identification and proper malnutrition diagnosis supported by care coordination, we were able to see a dramatic increase in the number of patients identified with malnutrition and referred to treatment.

- After 5 months of quality improvement, eCQM performance data were collected again (postimplementation of the quality improvement [QI] program) and evaluated to determine if the QI efforts was driving an improvement in clinical practice.
- Performance improved significantly (P<0.01) on the malnutrition eCQMs focused on completing a nutrition assessment within 24 hours of identification of malnutrition risk and ensuring documentation of a malnutrition diagnosis if it was identified.
- Other results of the QI efforts included:
  - Increase in the RDNs' own understanding of the importance of their work.
  - Elevation of the RDN role and of the Clinical Nutrition Department relationship with other departments and institution leadership; and
  - An increase in the visibility of nutrition assessments and identification of patient malnutrition across all clinical disciplines.

The implementation of the MQii framework, which includes the important component measures that are a part of this composite measure under review and the MQii Toolkit of quality improvement resources, has been effective in helping identify gaps and improving the care for malnourished patients at clinical facilities. By working collaboratively, the UPMC MQii multidisciplinary team was able to make malnutrition care at their facilities a top priority.

1. Danis K, Kline M, Munson M, et al. Identifying and managing malnourished hospitalized patients utilizing the malnutrition quality improvement initiative: the UPMC experience. J Acad Nutr Diet. 2019;119(9 Suppl 2):S40-S43.

National Hispanic Council on Aging (NHCOA)

On behalf of the National Hispanic Council on Aging (NHCOA), I am pleased to submit comments in support of MUC20-0032, the Global Malnutrition Composite Score.

The National Hispanic Council on Aging is committed to improving the health status of Hispanic older adults, their families, and caregivers. Achieving and maintaining excellent health should be a top priority at any age. Lack of meaningful access to quality health care also contributes to poor health outcomes for Hispanic older adults. Hispanic older adults disproportionately suffer from afflictions, such as diabetes and HIV with an estimated more than 80% having at least one chronic condition.

	Additionally, there is a high prevalence of malnutrition among hospitalized patients, but it frequently goes unrecognized compounding other health conditions. Up to 50% of all patients are at risk for or are malnourished at the time of hospital admission.1 Only 7% of patients are typically diagnosed with malnutrition during their hospital stay.2 Malnutrition has a significant impact on patient outcomes as malnourished hospitalized adults have a 54% higher likelihood of hospital 30-day readmissions than those who are well-nourished.3 Patients with a malnutrition diagnosis and nutrition care plan had 24% reduction in readmission risk vs those without a care plan for outlining intervention and treatment.[4] MUC20-0032 Global Malnutrition Composite Score includes four components that provide a framework of critical steps documenting the timely identification and treatment of patients with malnutrition or at risk for malnutrition. On behalf of the National Hispanic Council on Aging, we appreciate the opportunity to submit these comments in support of the adoption of MUC20-0032 Global Malnutrition Composite Score. References: 1. Wells JL and Dumbrell AC. Nutrition and Aging: Assessment and treatment of compromised nutritional status in frail elderly patients. Clin Interv Aging. 2006; 1(1):67-69. 2. Weiss AJ, Fingar KR, Barrett ML, Elixhauser A, Steiner CA, Guenter P, Brown MH. Characteristics of hospital stays involving malnutrition, 2013. HCUP Statistical Brief #210. Rockville, MD: Agency for Healthcare Research and Quality. Available at: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.pdf. 3. Fingar KR, Weiss AJ, Barrett ML, et al. All-cause readmissions following hospital stays for patients with malnutrition, 2013. HCUP Statistical Brief #218. December 2016. Agency for Healthcare Research and Quality, Rockville, MD. https://www.hcup- us.ahrq.gov/reports/statbriefs/sb218-Malnutrition-Readmissions-2013.pdf. 4. Valladares AF, et al. How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative. JPEN J Parenter Enteral Nutr. 2020;
Abbott	Abbott welcomes the opportunity to submit comments requesting CMS' adoption of MUC202030 Global Malnutrition Composite Score in the IQR. Abbott has a long history developing nutritional products, services and resources to help health professionals effectively address and manage those with, or at-risk for malnutrition in all care settings, including at home. We are committed to working with health professionals, providers and policy makers to raise awareness of malnutrition as a critical, costly, and largely under-appreciated health concern. Abbott has actively engaged with CMS on a variety of policy initiatives that support this vital goal. We appreciate CMS' ongoing recognition of malnutrition as a significant health crisis warranting attention.
Alliance of Wound Care Stakeholders	Dear MAP Coordinating Committee; On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit comments in support of MUC20-0032, the Global Malnutrition Composite Score. The Alliance is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote evidenced-based quality care and access to products and services for people with chronic wounds. One area that is important to our members is the adoption of wound care related quality measures, which is why we are supportive of this measure.

Many studies demonstrate correlations between malnutrition and elevated needs for continued medical interventions, higher costs of care and increased patient safety risks. For example, malnourished hospitalized patients experience slower wound healing, higher risks of infection and longer LOS.1,2 Quality Improvement (QI) associated with a 36% increase in malnutrition diagnosis in targeted service lines (13.5% vs 18.4%, p-value<0.001, with the greatest significant increases observed in the general medical (10.8 vs. 16.25, p-value<0.001) and pulmonology (16.8 vs. 24.0, p-value=0.033) units. As many as 45% of patients identified as at malnutrition risk did not receive an RDN assessment, indicating a gap in patient nutrition care in some service lines.3

Malnutrition is a leading cause of morbidity and mortality, especially among older hospitalized adults. Hospitalized patients who are malnourished have a greater risk of complications, falls, pressure ulcers, infections, and readmissions, and experience 4 to 6 days longer length of stay. The endorsement and inclusion of MUC20-0032, Global Malnutrition Composite Score in the Hospital Inpatient Quality Reporting (IQR) program will ultimately improve patient care outcomes through standardized identification and treatment of malnutrition.

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments in support of the adoption of MUC20-0032, Global Malnutrition Composite Score. Please contact me if you have any questions regarding our endorsement of this important measure.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

1. Barker L, Gout B, Crowe T, et al. Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. Int J Environ Res Public Health 2011;8:514–27
2. Pratt KJ, et al. Impact of an interdisciplinary malnutrition quality improvement project at a large metropolitan hospital. BMJ Open Qual. 2020;9(1)
3. Improving Malnutrition Diagnosis at an Academic Medical Center: A Nutrition-focused Quality Improvement Program – Society for Medical Decision-Making Annual Conference 2020.

American Society for Parenteral and Enteral Nutrition	January 20, 2021 Dear NQF, On behalf of the American Society for Parenteral and Enteral Nutrition (ASPEN), we appreciate the opportunity to submit comments in support of NQF #3092, the Global Malnutrition Composite Score. As multi-disciplinary clinicians and researchers, we have been advocating for identification, prevention, and treatment of hospital-based malnutrition since the inception of our organization in 1976. ASPEN is dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism. ASPEN is an interdisciplinary organization whose members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition. With more than 6,000 members from around the world, ASPEN is a community of dietitians, nurses,

pharmacists, physicians, scientists, students, and other health professionals from every facet of nutrition support clinical practice, research, and education. We have significant experience and understanding of the processes of care for identification and treatment that are outlined and recommended in the malnutrition composite score. In 2012, ASPEN initiated Malnutrition Awareness Week™, a week of education and intervention, which in 2020 included 115 national and international organizations which potentially reached over 1 million clinicians and nutrition professionals. As part of this effort, the US Senate has approved Senate Resolution 716:
(1) which designates the week of October 5 through October 9, 2020, as ``Malnutrition Awareness Week™'';
(2) recognizes registered dietitian nutritionists and other nutrition professionals, health care providers, social workers, advocates, caregivers, and other professionals and agencies for their efforts to advance awareness, treatment, and prevention of malnutrition;
(3)(A) recognizes the importance of existing Federal nutrition programs for their role in combating malnutrition; and
(B) supports emergency funding for those critical Federal nutrition programs for the duration of the Coronavirus Disease 2019 (COVID-19) pandemic. ASPEN has also developed a widely used nutrition care pathway to help guide processes from hospital admission to discharge.

ASPEN has been involved in many quality and research efforts bringing forth improvements in malnutrition care, impact of better care for hospitalized and critical care patients, and documentation of these diagnoses. These include:
• Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition) 2012
• Feasibility of accessing data in hospitalized patients to support diagnosis of malnutrition by the Academy-A.S.P.E.N. malnutrition consensus recommended clinical characteristics 2013
• Critical Role of Nutrition in Improving Quality of Care: An Interdisciplinary Call to Action to Address Adult Hospital Malnutrition 2013
• Nutrition Screening and Assessment in Hospitalized Patients: A Survey of Current Practice in the United States 2014
• Addressing Disease-Related Malnutrition in Hospitalized Patients: A Call for a National Goal 2015
• Malnutrition identified by Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition is associated with more 30-day readmissions, greater hospital mortality, and longer hospital stays: a retrospective analysis of nutrition assessment data in a major medical center. 2018
• Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition consensus malnutrition characteristics: usability and association with outcomes 2019

ASPEN also partnered with the Agency for Healthcare Research and Quality to develop data briefs on malnutrition in hospitalized patients and impact on hospital readmissions. This work has helped quantify the issue on a national level and helped us measure the growth of diagnosed malnutrition in this population. ASPEN is involved with a current AHRQ Technical Advisory Panel continuing to look at these issues. These reports clearly demonstrate higher costs and increased readmissions in those patients identified with malnutrition.
• Non-Maternal and Non-Neonatal Inpatient Stays in the United States Involving Malnutrition, 2016 (PDF)
• Characteristics of Hospital Stays Involving Malnutrition, 2013 (PDF , HTML)
• All-Cause Readmissions Following Hospital Stays for Patients With Malnutrition, 2013 (PDF , HTML)
ASPEN's efforts in reporting on the impact of malnutrition and the importance of proper identification and treatment of malnutrition demonstrate how critical it is that hospitals focus on

this condition. The steps in the process of detecting, diagnosing, documenting, care planning, preventing, and treating malnutrition need to be measured in hospitalized patients. This global composite measure as outlined in NQF # 3092 provides an opportunity to standardize processes of care and data collection to track and monitor quality of care for malnourished hospitalized patients and those at risk, and would be a critical addition to existing measures on which hospitals currently focus. ASPEN highly supports approval of this composite measure.

Sincerely,

Peggi Guenter, PhD, RN, FAAN, FASPEN
Senior Director, Clinical Practice, Quality, and Advocacy
ASPEN
peggig@nutritioncare.org

New Hanover Regional Medical Center

As a Clinical Nutrition Manager and representative of my organization, New Hanover Regional Medical Center, I have had the opportunity of implementing the four measures under consideration (MUC20-0032-Global Malnutrition Composite Score) and have seen firsthand the value that they bring to our organization, staff, patients, and community.

I am certain you are very well aware of the prevalence of malnutrition in our nation and the effect that it has on the immune system, patient recovery time, utilization of hospital resources and an individual's ability to return to a normal quality of life post hospitalization, at a minimum.

In 2016, New Hanover Regional Medical Center imbedded these four measures into our Electronic Medical Record, and this is where our journey through the transitions of care truly began. Since that time, we have had the unique experience and privilege of bridging the gap between the hospital and home for our malnourished patients. Additionally, we have been able to use this population to pilot a food insecurity program, as many times these two populations overlap. Due to the enormous success of our malnutrition transitions of care program, we now visit these malnourished and often food insecure seniors in their homes following hospital discharge.

In 2019, we created a workflow that deploys our Clinical Outreach Registered Dietitian right into the homes of our malnourished community members that need him the most. These patients have been identified and followed by our inpatient staff members using these four measures on every patient that is admitted to our organization that is at nutrition risk. I cannot adequately emphasize in writing the importance of identifying these patients upon admission, implementing early nutrition intervention by a Registered Dietitian, appropriately documenting the malnutrition diagnosis and consistently communicating the plan of care for long-term care coordination.

These 4 measures have helped us implement more timely and appropriate care for malnourished patients and improve communication across the continuum of care. Our outcomes demonstrate the significant impact that we have made on this underserved population. We have seen a 50 % improvement in our malnutrition capture rate, a 547% improvement in appropriate diagnosis of malnutrition, a 34.7% improvement in Nutrition Assessment within 24 hours of screening and a 19% reduction in 30-day readmissions of malnourished patients.

Therefore, I implore you to endorse these measures for inclusion in the CMS Hospital Inpatient

	Quality Reporting Program. Sincerely, Angela L. Lago MS, RD, LDN Clinical Nutrition Manager New Hanover Regional Medical Center Wilmington, NC
Association of American Medical Colleges (AAMC)	The Hospital MAP conditionally supported for rulemaking the malnutrition electronic clinical quality measure (eCQM) composite (MUC2020-0032) pending NQF endorsement. The AAMC agrees that malnutrition is a critical clinical quality area not directly addressed by measures in the Hospital Inpatient Quality Reporting (IQR) Program, and that there is value in identifying and treating malnutrition upon admission to the hospital. We believe that NQF endorsement of the measure is critical and should be completed before the measure is proposed for addition to the IQR. The AAMC agrees with the MAP's recommendation.
Healthcare Nutrition Council	Centers for Medicare & Medicaid Services Department of Health and Human Services 7500 Security Boulevard Baltimore, MD 21244 January 20, 2021 Re: MAP MUC 2020 Comment Period – MUC20-0032 – "Global Malnutrition Composite Score" To Whom It May Concern, The Healthcare Nutrition Council (HNC) supports inclusions of the Measure Under Consideration (MUC) MUC20-0032 "Global Malnutrition Composite Score" for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program. HNC is an association representing manufacturers of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), parenteral nutrition (PN) formulas, supplies and equipment. Our mission is to improve health by advancing policies that address and raise awareness of nutrition and its impact on patient outcomes and healthcare costs. Our organization aims to promote nutritional screening, diagnosis, assessment, appropriate and timely clinical nutrition interventions, as well as patient access to specialized nutrition support products and services throughout the continuum of care. HNC is pleased to see the MAP Hospital Workgroup supported the Global Malnutrition Composite Score (MUC20-0032) measure in the Hospital IQR Program. As CMS is aware, malnutrition is widely recognized as having a significant role in health outcomes and healthcare costs. Addressing malnutrition is essential to improving quality of care and outcomes for patients. To just name a few important considerations, malnutrition has been shown to lead to increased complications, longer hospitalizations and more readmissions for patients being treated in facility settings. In addition, malnutrition is a risk factor for other adverse clinical events, such as falls, and is also tied to higher rates of stroke, heart failure, cancer, and COPD. It is important that CMS and others include robust nutrition measures in its quality reporting programs, including and especially the IQR Program, which tracks care for acutely ill, hospitalized

	patients. HNC therefore offers its strong support for the addition of the Global Malnutrition Composite Score in the IQR program. HNC also encourages all stakeholders to continue advancing other nutritional-related measures for inclusion in CMS and other quality programs, and we stand ready to work with all stakeholders on this important initiative. HNC thanks CMS for allowing us the opportunity to provide feedback on the inclusion of these measures. Should you wish to discuss these comments further, please contact Berit Dockter at bdockter@healthcarenutrition.org. Sincerely, Robert Rankin Executive Director
American Hospital Association	The AHA disagrees with the MAP's recommendation of Conditional Support and instead suggests a recommendation of Do Not Support. While malnutrition is associated with poorer patient outcomes, this measure does not sufficiently address CMS's Meaningful Measures priorities, and thus should not be considered for inclusion in CMS quality reporting programs. The developer contends that this composite measure meets the Meaningful Measures priority area of Admissions and Readmissions even though it does not evaluate patient admissions in any way. We struggle to understand how a measure can be labeled an "admission/readmission" measure when it merely has an association or relationship with length of stay or readmissions. Even more puzzling and troubling is that while one can draw a conceptual association between addressing malnutrition and readmission rates, the empirical evidence provided to support that relationship is extremely limited. Indeed, half of the components of the composite (screening for malnutrition and completion of nutrition assessment) did not receive favorable ratings in terms of evidence presented. Even if there were sufficient evidence supporting the link between nutrition and admissions/readmissions, we seriously question whether this measure addresses a high-priority aspect of care quality in inpatient hospitals. It is not a measure of whether patients receive adequate nutrition while in the hospital, but rather a process measure that may – or may not – have a particularly strong linkage to a larger public health issue. Certainly, there are many important aspects of care that one can measure, but the whole point of having a Meaningful Measures framework is to help CMS and the field judge whether even worthy topics should be included in programs given the balance of other important competing priorities. If CMS seeks to create a meaningful, widely applicable, and streamlined measure set for the IQR, we do not believe this measure would "make the cut."
Tampera General Hospital	To: The NQF MAP Hospital Workgroup Thank you for the opportunity to offer my comments supporting the Global Malnutrition Composite Score, NQF #3092. My leadership role in clinical nutrition within a world-class academic medical center and health system, has permitted direct experience with implementing valuable patient care processes outlined and recommended in the malnutrition composite score. Below I will outline how our hospital pursued improvements and change supported by the principles of the Malnutrition Quality Improvement Initiative (MQii) and the many impacts these improvements had on our patients and staff. Given the increased prevalence of disease related malnutrition and its accompanying poor health outcomes, prolonged stays, risk of re-admission and burdensome cost, the need to identify and

treat malnutrition became more pronounced. The need for aggressive intervention is heightened in our new SARS-CoV-2 environment. Consider that in Wuhan, China, 52.7% of patients with COVID-19 were malnourished. Contemporary hospitals and responsible healthcare professionals must apply policies and process improvement strategies to address malnutrition. We launched an all-out attack on malnutrition in our hospital organization using the MQii. The MQii process helped uncover gaps in our service for which we built processes to close care gaps and support improved outcomes. Details of our work was published in peer reviewed articles in 2019, and 2020 (below). We also provided in-depth collaboration on the ASPEN Storyboard and presented at the Institute for Healthcare Improvement demonstrating outcomes evidence on the economic value of nutrition. The latter projected Medicare cost savings of $580 million when utilizing nutrition to optimize patient outcomes

Our malnutrition journey began with engaging a multidisciplinary committee to support and implement a validated screening instrument into our electronic medical record (EMR). As a result, malnourished patients would be screened within 24hrs. We also changed our policy to support nutritional assessment of malnourished patients, by and RDN, within 24 hours of the electronic notification. We partnered with our I.T department to build the ASPEN/Academy criteria for malnutrition diagnosis into the EMR and populate our care plan documentation. We began seeing patients with colorectal cancer (have since also added HIPEC patients) in the pre-admission testing area. We provide them with nutrition education and pre-surgical immunonutrition at no cost. We implemented standard TPN guidelines into the EMR, added an order set for enteral nutrition, and most recently piloted volume-based feeding (VBF) in the neuro ICU. Given great outcomes, we have been asked to implement VBF in all ICUs and our stepdown units.

We petitioned and were granted order writing privileges. We also obtained physician agreement to add nutritional supplements to the medication administration record. Together, these prevented delays in the delivery of nutritional supplements to our malnourished patients. We successfully wrote and obtained a grant from BCBS to provide malnourished patients, identified as food insecure, with home delivered meals post discharge.

Our dietitians have undoubtedly been recognized by the organization, we obtained a hospital leadership award, and a leadership award from our nursing staff. We were also asked to conduct the keynote address for our graduating nurse residents as well as lead one of the nursing counsels. We have since created a clinical ladder with HR and leadership approval and at least 90% of our RDNs now have advanced credentials and/or specialty certification. Three members of our RD team have been accepted into the hospital's leadership programs and one of our RDNs serves as chairperson of the hospital's leadership alumni.

It continues to take all hands-on deck to create lasting change and influence policy makers. Collaboration across the hospital was required to implement the MQii and the corresponding quality measures. That enabled us to address the gaps uncovered and helped to raise awareness and support from our hospital leaders, medical staff, and interdisciplinary teammates. Our processes allowed the identification of malnutrition to be brought to the forefront of care.

Published works:

Fitall E, Pratt K, McCauley M, Giedre A, Heck T, Hernandez B. Improving Malnutrition in Hospitalized Older Adults: The Development, Optimization, and Use of a Supportive Toolkit. Jand.2019;2(119):25-31

Jones K, Hernandez B, Blancato R, Blankenship J, Mitchell K. Impact of an interdisciplinary malnutrition quality improvement project at a large metropolitan hospital. BMJ Open Quality. 2020;1-7

Morrison Healthcare

To: The NQF Prevention and Population Health Endorsement Committee:

Morrison Healthcare appreciates the opportunity to submit comments in support of NQF #3092, the Global Malnutrition Composite Score. We are a food service and clinical nutrition company, contracted with 900+ hospitals to employ and manage over 2,000 registered dietitian nutritionists (RDNs). We have implemented the components of the Global Malnutrition Composite Score in hospitals across the United States, ranging from small community hospitals to large tertiary care medical centers, having first-hand understanding of their impact on patient outcomes and well-being.

Malnourished patients are at risk for poor health outcomes and increased resource utilization, including longer length of stay and increased readmission rates , , , . One reference provides a concise summary of literature linking malnutrition to nosocomial infections, hospital-acquired conditions, readmissions, length of stay, and pressure injuries . In addition to increasing costs, malnutrition leads to a reduced quality of life for our nation's seniors. Most want to be home engaging in a healthy, productive life rather than undergoing repeated hospitalizations and worrying about the burden they cause to their families to care for them after complications that could be prevented by having a better nutritional status.

Morrison Healthcare has set a high priority on making improvements in quality of care guided by the malnutrition care process that is addressed by the component measures in the composite with the support from the Malnutrition Quality Improvement Initiative (MQii) resources and team. Morrison RDNs have been aggressively tackling screening for malnutrition risk upon admission, completing a nutrition assessment for patients found at risk of malnutrition, documenting the malnutrition diagnosis for those found to be malnourished, and developing a nutrition care plan for malnourished patients.

Here are some examples of our success:
Evaluating data collected from Morrison Healthcare hospitals during fiscal year 2020 (October 2019 – September 2020) on important key metrics shows the benefit of our aggressive focus on identifying and treating malnourished patients. Eighty-nine hospitals collecting data on malnourished patients reported an average length of stay of 9.17 days versus the national average of 10 days. Sixty-seven hospitals reported a 19% readmission rate for malnourished patients versus the national average of 23% . Forty-five hospitals reported over 8% of discharges (with 8% being the national average) coded for malnutrition with 17 hospitals reporting over 15% of discharges coded for malnutrition.

One medium-sized hospital in Tennessee completed a quality improvement study on the malnutrition screening process. Its study resulted in an RDN-led screening method using a validated screening tool plus a brief examination for signs and symptoms of muscle wasting and fat loss. Patients who screened at risk for malnutrition received a referral for a full nutrition assessment by a dietitian. The result of this study was the percentage of patients identified with malnutrition nearly tripled. RDN patient visits have increased by 29% since implementation.

As outlined in the 2019 Special Supplement on the Malnutrition Quality Improvement Initiative (MQii) to the Journal of the Academy of Nutrition and Dietetics (JAND), Morrison Healthcare studied the accuracy of malnutrition diagnosis when RDNs completed Nutrition Focused Physical Exams (NFPE). The study results showed that among the 691 patients included in the study, 57% were identified with a higher degree of malnutrition once NFPE was completed .

Morrison RDNs at a large teaching hospital located in Virginia worked with their Department of

Medicine to investigate the prevalence of malnutrition in sepsis and the impact it has on clinical and financial outcomes in the most critically ill patients. They published their results in 2020, showing that out of 1000 consecutive patients, 9.8% were diagnosed with malnutrition. Of those patients, 54% had severe malnutrition based on the American Society for Parenteral and Enteral Nutrition (ASPEN)/Academy of Nutrition and Dietetics (AND) criteria. Patients with malnutrition were older (75 years +/-15 years vs 67 years +/- 21 years, $p < 0.001$). Patients with malnutrition had a longer length of stay (average 9 vs 7 days, $p = 0.0018$) and higher total cost (US $27,431 vs US $18,785, $p < 0.0001$). Patients without malnutrition were more likely to be discharged home than were those with malnutrition (61.4% vs 40.8%, $p < 0.001$). Only 32.6% of patients diagnosed with either moderate or severe malnutrition were referred to a dietitian by a physician; the remaining 67.3% were all diagnosed based on mandatory RDN-led assessments .

These examples above show how the implementation of the MQii framework, which includes the important component measures that are a part of this composite measure under review and the MQii Toolkit of quality improvement resources, has been effective in helping identify gaps and improving the care for malnourished patients at Morrison Healthcare clinical facilities.

Sincerely,
Peggy O'Neill, Vice President Nutrition & Wellness

Allard JP, Keller H, Jeejeebhoy KN, et al. Malnutrition at Hospital Admission-Contributors and Effect on Length of Stay: A Prospective Cohort Study From the Canadian Malnutrition Task Force. JPEN J Parenter Enteral Nutr. 2016;40(4):487-97.

Kruizenga H, Van keeken S, Weijs P, et al. Undernutrition screening survey in 564,063 patients: patients with a positive undernutrition screening score stay in hospital 1.4 d longer. Am J Clin Nutr. 2016;103(4):1026-32.

Guerra 3 RS, Sousa AS, Fonseca I, et al. Comparative analysis of undernutrition screening and diagnostic tools as predictors of hospitalisation costs. J Hum Nutr Diet. 2016;29(2):165-73.

Gomes F, Emery PW, Weekes CE. Risk of Malnutrition Is an Independent Predictor of Mortality, Length of Hospital Stay, and Hospitalization Costs in Stroke Patients. J Stroke Cerebrovasc Dis. 2016;25(4):799-806.

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Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. ONLINE. August 30, 2018. U.S. Agency for Healthcare Research and Quality. Available: www.hcup-us.ahrq.gov/reports.jsp.

Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. ONLINE. August 30, 2018. U.S. Agency for Healthcare Research and Quality. Available: www.hcup-us.ahrq.gov/reports.jsp.

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McLaughlin J, Chowdhury N, et al. Clinical outcomes and financial impacts of malnutrition in sepsis. Nutr Health. 2020 Sep;26(3):175-178. doi: 10.1177/0260106020930145. Epub 2020 Jun 22.

International Council on Active Aging

The International Council on Active Aging (ICAA) is appreciative of this opportunity to share its comments about the U.S. Centers for Medicare and Medicaid Services' (CMS) Measure Under Consideration (MUC) MUC20-0032 Global Malnutrition Composite Score and inclusion of the measure in the Hospital Inpatient Quality Reporting (IQR) Program. The ICAA connects a community of like-minded organizations and professionals—including over 10,000 U.S. members—who share the goals of changing society's perceptions of aging and improving the quality of life for aging Baby Boomers and older adults.

ICAA believes that the concept of wellness moves the definition of health and well-being away from a mindset based in the management of disease and into the areas of prevention and proactive strategies, including physical wellness. Part of physical wellness is choosing healthy foods with adequate nutrition. Yet for many older adults, their physical wellness is compromised by malnutrition, with up to one out of two older adults either at risk of becoming or already malnourished.1,2 To help address this we strongly support CMS adopting the Global Malnutrition Composite Score for inclusion in the Hospital IQR Program.

The ICAA is dedicated to changing the way we age by uniting professionals in the retirement, assisted living, fitness, rehabilitation, and wellness fields to dispel society's myths about aging. One of these myths is that all older adults will naturally become frail and lose muscle strength and function as they age. However, for many older adults it may be malnutrition more than age itself that is the barrier to their successful and active aging. This is why the World Health Organization includes addressing malnutrition as one of its 13 fundamental strategies to help maintain older adult functionality.3

Older adults may be at-risk for or become malnourished in any setting. Yet, the trigger of a hospitalization can exacerbate and accelerate malnutrition and their risk of malnutrition, particularly during the global COVID-19 pandemic where disparities and social isolation have further compounded older adults access to healthy foods and risk for malnutrition. Implementation of the Global Malnutrition Composite Score will help provide the framework necessary for older adults to pursue their goals of successful and active aging. Please consider immediately adopting the measure into the IQR Hospital program.

1. Kaiser MJ, Bauer JM, Rämsch C, et al. Frequency of malnutrition in older adults: A multinational perspective using the mini nutritional assessment. J Am Geriatr Soc. 2010;58(9):1734-1738. doi:10.1111/j.1532-5415.2010.03016.x.
2. Izawa S, Kuzuya M, Okada K, et al. The nutritional status of frail elderly with care needs according to the mini-nutritional assessment. Clin Nutr Edinb Scotl. 2006;25(6):962-967. doi:10.1016/j.clnu.2006.05.006.
3. World Health Organization. Integrated Care for Older People (ICOPE) Guidelines on Community-level Interventions to Manage Declines in Intrinsic Capacity. 2017. Available at: https://static.abbottnutrition.com/cms-prod/anhi-2017.org/img/ICOPE%20Infographic_tcm1423-128740.pdf

Defeat Malnutrition Today	Defeat Malnutrition Today, a coalition of over 100 national, state and local organizations dedicated to ending older adult malnutrition, appreciates the opportunity to offer comments to NQF. We strongly support MUC 20-0032, the Global Malnutrition Composite Score, and urge its inclusion in the IQR. As a coalition with many organizations that serve older adults who have just been discharged from acute care settings, we see the importance of diagnosing malnutrition in patients and creating a nutrition care plan while they are in acute care. That way, these patients can be directed to the nutrition services and supports they may need, whether those services are back home in their communities or in rehabilitation or long-term care facilities. Further, a diagnosis and comprehensive nutrition care plan are vital to ensuring that these patients do not return to acute care settings, since malnourished patients have higher readmissions rates (Sharma et al, 2017). In general, malnutrition affects approximately 20 percent to 50 percent of admitted hospital patients in the US. (Barker et al, 2011). Malnourished patients are more likely to develop a healthcare-acquired condition such as pressure ulcers. They are also more likely to have delayed wound healing, decreased respiratory and cardiac function, muscle wasting, and functional loss, in turn increasing their risk of falls, longer length of hospital stays, and higher treatment costs. In short, diagnosing and treating malnutrition leads to better patient outcomes and lowered healthcare costs. Adoption of the Global Malnutrition Composite Score by the IQR has the potential to offset these negative impacts of malnutrition through quick screening, identification, diagnosis and treatment. NQF should endorse this measure. References Barker, L. A., Gout, B. S., Crowe, T. C. (2011). Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. International Journal of Environmental Research and Public Health, 8(2), 514-527. Sharma, Y., Miller, M., Kaambwa, B., et al. (2017). Malnutrition and its association with readmission and death within 7 days and 8–180 days postdischarge in older patients: a prospective observational study. BMJ Open, 2017(7).

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0032
Other Measure Identification Numbers	N/A
Title	Global Malnutrition Composite Score
Program	Medicare and Medicaid Promoting Interoperability Program for Eligible Hospitals (EHs) or Critical Access Hospitals (CAHs)
Workgroup	MAP Hospital
In what state of development is the measure?	Fully Developed
State of Development Details	Validity Testing. In accordance with CMS requirements, both the individual components and the overall composite have been tested for reliability and validity. The composite measure score and components were tested with a patient sample of 37,450 records from 27 hospitals across 6 states. Minimum patient inclusion criteria was age 65 years and older, length of stay greater than or equal to 24 hours, and admission to malnutrition screening time less than 48 hours from admission. A summary of both validity and reliability testing are included below, but additional details are provided in the appendix section corresponding to this row. Validity testing was completed by constructing a regression model to demonstrate that the predictability of the model significantly improved when the components in aggregate were included into the model over standard predictors of these outcomes such as patient characteristics and primary diagnoses. The findings of the test demonstrated that malnutrition indicators are significantly related to LOS and Readmissions after controlling for the other variables that were included in the model (patient demographics and primary diagnosis) known to be predictive of those outcomes. The R2 statistic for the LOS model was 0.25, and the c-statistic for the 30-day readmissions model was 0.584. When compared to the predictability of other outcome models used for instance in CMS' HCC risk-adjustment models, our model's components were stronger predictors and are comparable to those diagnosis-based models already in place. Reliability Testing. A separate and more recent dataset was constructed to complete additional testing for the composite measure reliability. A total of 179,336 patients age 65 years and older were included in the testing population across 56 acute care hospitals in 10 states. Composite measure reliability was assessed using the variance components—extracted from a linear mixed effects (LME) model—to calculate the intraclass correlation coefficient (ICC). The LME framework was employed, because it accommodates inclusion of both fixed and random effects, the latter of which account, statistically, for the correlated or non-independent nature of measures that are hierarchically nested within health systems (N = 10) and practice sites (N = 56). The model variance (σ2) can then be partitioned into components that are, in turn, used to calculate the Cowitch case minimums applied, the result was an ICC of 0.839 which reflects an acceptable level of reliability and ability to detect meaningful differences among provider groups. Additional testing information is provided in the attachment: Global Malnutrition Composite Measure_Testing Attachment.
Measure Description	Composite measure consisting of 4 component measures of optimal malnutrition care focuses on adults 65 years and older admitted to inpatient service who received care appropriate to their level of malnutrition risk and/or malnutrition diagnosis if identified. Appropriate care for inpatients includes to malnutrition risk screening, nutrition assessment for that at-risk, and proper malnutrition severity indicated along with a corresponding nutrition care plan that recommends treatment approach.
Numerator	The Global Malnutrition Composite Score is comprised of four component measures which are scored separately and whose population is sourced from the overall composite measure denominator. 1. Screening for malnutrition risk at admission. 2. Completion of a

	nutrition assessment for patients who screened for risk of malnutrition. 3. Appropriate documentation of malnutrition diagnosis for patients identified with malnutrition. 4. Development of a nutrition care plan for malnourished patients. The composite measure score is calculated by summing and then averaging the performance scores for each of the four component measures included in the overall composite measure. Each component measure is a proportion measure.
Denominator	The measure population from which the composite's component measures are sourced from are patients age 65 years and older who are admitted to an acute inpatient hospital.
Exclusions	1. All Four Component Measures: patients with a length of stay less than 24 hours; 2. Component Measure #1 only: admission to screening time interval greater than 48 hours; 3. Component Measure #3 and #4 only: discharge status of hospice or left against medical advice.
Measure type	Composite
What is the NQF status of the measure?	Submitted
NQF ID number	3592
Year of next anticipated NQF CDP endorsement review	2020
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as endorsed by NQF?	N/A
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	EHR
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	Facility
In which setting was this measure tested?	Hospital inpatient acute care facility
What NQS priority applies to this measure?	N/A

What one primary meaningful measure area applies to this measure?	Admissions and readmissions to hospitals
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote effective communication and coordination of care
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Other, Nutrition
What is the target population of the measure?	All adult inpatients age 65 years and older regardless of payer in need of malnutrition screening, nutrition assessment if found at-risk of malnutrition, or a malnutrition diagnosis and care plan if found malnourished by assessment.
Is this measure an eCQM?	Yes
If eCQM, enter Measure Authoring Tool (MAT) number	986
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	Yes
Comments	Per submitter e-mail 7/8/2020: "We will be submitting Bonnie Testing Attachment shortly as we are working with CMS's technical contractor in the JIRA to complete the last step of the Bonnie testing."
Measure steward	Academy of Nutrition and Dietetics
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Sharon McCauley; 312-899-4823; smccauley@eatright.org
Primary Submitter Contact Information	Angel Valladares; 202-446-2242; avalladares@avalere.com
Long-Term Measure	N/A

Steward Contact Information	
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A

Evidence that the measure can be operationalized	Three published studies describe implementation of the component measures of this composite measure. One study outlined the usability and feasibility of the composite measure components (Doley, 2018). A second published study reported on the testing of the composite's component measures and how the testing site used the testing results to implement improvements to hospital workflow (Nepple, 2019). Another study published the measure performance across a learning collaborative of US hospitals as well as how the measures were used to assess quality improvement (Valladares, 2020). REFERENCES: Doley J, Phillips W, Talaber J and Leger-LeBlanc G. Early Implementation of Malnutrition Clinical Quality Metrics to Identify Institutional Performance Improvement Needs. Journal of the Academy of Nutrition and Dietetics. 2018; Article in Press. doi.org/10.1016/j.jand.2018.02.020. Nepple K, Tobert C, Valladares A, Mitchell K, Yadrick M. Enhancing identification and management of hospitalized patients who are malnourished: a pilot evaluation of electronic quality improvement measures. J Acad Nutr Diet. 2019;119(9S2):S32-S39. Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, Mccauley S. How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative. JPEN J Parenter Enteral Nutr. 2020.
How is the measure expected to be reported to the program?	eCQM
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	A bootstrap resampling methodology was employed to generate a 95% confidence interval around the composite score mean. The 95% confidence interval will then be used to group providers into performance categories (Low, Medium, High).Participating hospitals were categorized into three tiers that reflect those whose composite measure performance

	scores were above, overlapped with, or were below the 95% estimate generated in the bootstrap analysis. If a hospital's composite score was assigned a Tier 3 score it was above the estimated confidence interval and implies that the specific hospital's performance was above the average of the estimate developed from the aggregate of all reporting sites. A hospital receiving a Tier 2 score means their performance was not meaningfully different than the estimated mean. Finally, a hospital receiving a Tier 1 score implies that their composite performance score fell below the mean estimate interval reflective of lower than expected performance. Among hospitals that meet the case minimum of 20 patients and at least 3 reportable measures, 44.7% of hospitals were in the highest performing Tier 3, 14.9% were in Tier 2, and 40.4% were in Tier 1.January 1, 2019 through December 31, 2019 [Table]Category = Tier 3, All Participants Number of Hospitals = 22, 39.3%, Participants N greater than or equal to 20 Number of Hospitals = 21, 44.7%Category = Tier 2, All Participants Number of Hospitals = 3, 5.4%, Participants N greater than or equal to 20 Number of Hospitals = 7, 14.9%Category = Tier 1, All Participants Number of Hospitals = 31, 55.3%, Participants N greater than or equal to 20 Number of Hospitals = 19, 40.4%This tiering approach informed by the bootstrap sample derived from the observed performance measures was used to appropriately distinguish sites with varying degrees of performance among the component measures. These differences ultimately translated to variation in performance on the overall composite measure. Our specific sample of sites is relatively homogeneous because the participating hospitals have been targeting improvement on these quality measures for 1-3 years.
Unintended consequences	No unintended consequences have been reported by participating hospitals over 3 years of performance reporting.
Which clinical guideline(s)?	The components of this composite measure are supported by multiple clinical guidelines that recommend the following: (1) malnutrition screening for patients admitted into the acute inpatient care setting; (2) nutrition assessment for patients at-risk of malnutrition in order to form the basis for an appropriate nutrition intervention; (3) appropriate recognition, diagnosis, and documentation of the nutrition status of a patient in order to address their condition with an appropriate plan of care and communicate patient needs to other care providers. By completing a malnutrition screening early during the patient's admission, patients at-risk of malnutrition are identified earlier and can be referred to a dietitian to complete a nutrition assessment. A completed nutrition assessment for patients at-risk of malnutrition (typically first identified by malnutrition screening around admission time) facilitates subsequent development of a nutrition care plan that includes appropriate interventions to address the patient's malnutrition. The American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) recommends the following: 1. Screening for nutrition risk is suggested for hospitalized patients (Evidence Grade E); 2. Nutrition assessment is suggested for all patients who are identified to be at nutrition risk by nutrition screening (Evidence Grade E); 3. Nutrition support intervention is recommended for patients identified by screening and assessment as at risk for malnutrition or malnourished. (Grade Evidence C). REFERENCES: Mueller C, Compher C & Druyan ME and the American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) Board of Directors. A.S.P.E.N. Clinical Guidelines: Nutrition Screening, Assessment, and Intervention in Adults. J Parenter Enteral Nutr. 2011;35: 16-24. The British Association for Parenteral and Enteral Nutrition recommends the maintenance of documentation for all individuals including results of nutritional screening and assessments (which include malnutrition findings), along with consequent action plans and treatment goals. If the patient is transferred to another care setting, this information should be readily available to all new caregivers to ensure continuity of care. British Association for Parenteral and Enteral Nutrition. Malnutrition Matters, A Toolkit for Clinical Commissioning Groups and providers in England. Published 2012. Retrieved from: http://www.bapen.org.uk/pdfs/bapen_pubs/bapen-toolkit-for-commissioners-and-providers.pdf. A consensus statement from the Academy of Nutrition and Dietetics states that the registered dietitian's (RD's) assessment of critically ill adults should include, but not be limited to, the following: Food and Nutrition-Related History,

	Anthropometric Measurements, Biochemical Data, Medical Tests and Procedures, Nutrition-Focused Physical Findings, Client History. Assessment of the above factors is needed to correctly diagnose nutrition problems and plan nutrition interventions. Inability to achieve optimal nutrient intake may contribute to poor outcomes. Academy of Nutrition and Dietetics. CI: Nutrition Assessment of Critically Ill Adults 2012. Academy of Nutrition & Dietetics Evidence Analysis Library. Published 2012. Retrieved from: http://www.andeal.org/topic.cfm?menu=4800.
Briefly describe the peer reviewed evidence justifying this measure	Nationwide analysis of hospitalizations with malnutrition diagnoses concluded that 8% of all non-neonatal and non-maternal adult hospitalizations were coded for a diagnosis of malnutrition. Furthermore, malnourished patients experienced up to 5x risk of in-hospital mortality, up to 2x higher hospital costs, up to 2x longer length of stay, and 55% higher readmissions than discharges without malnutrition. (Barrett, 2018). Recently published research suggests that adopting malnutrition standards of care is a feasible and valuable endeavor for hospitals to undertake. Multiple studies have shown that optimal malnutrition care quality improvement programs improve care coordination between clinical disciplines responsible for nutrition care and that those improvements are associated with outcomes (Valladares, 2020; Danis, 2019; Nepple, 2019; Sriram, 2018). A cost evaluation was conducted on one of the quality improvement programs, savings in terms of avoided hospital readmissions and reduced patient length of stay for patients in the quality improvement program totaled up to $4.8 million (Sulo, 2017). Clinical evidence and best practices support the need for quality measures that incentivize early identification, diagnosis, intervention, and effective transitions of care for hospitalized patients who are at-risk or malnourished (McCauley, 2019). Malnutrition risk identified in patients through a malnutrition screening was able to predict certain patient outcomes including length of stay, mortality, and post-operative complications. (Sauer, 2019; Silver, 2018; Allard, 2016; Khalatbari-Soltani, 2016; Kruizenga, 2016; Agarwal, 2013). A large national study understanding inpatient data from US hospitals, demonstrated that as many as 1 in 3 hospitalized patients are at-risk of malnutrition according to validated screening (Sauer, 2019). The peer reviewed evidence cited for this measure also supports the assessment of patients at-risk of malnutrition via the completion of a nutrition assessment that can confirm malnutrition and initiate a care plan recommending appropriate interventions (Hudson, 2018). Multiple studies have reported patient outcomes associated with malnutrition when identified by nutrition assessment, was independently associated with higher hospital mortality, higher incidence of infection, and an increased risk of readmission (Hiller, 2017; Lew, 2016). Additionally, a recently published study demonstrated that malnourished patients were older (61 vs 58 years, P < .0001), had longer LOS (15 vs 12 days, P = .0067) and were more likely to be readmitted within 30 days (40% vs 23%, P < .0001). In adjusted models, 30-day readmissions (odds ratio [OR] 2.13, 95% confidence interval [CI] 1.82-2.48) and hospital mortality (OR 1.47, 95% CI 1.0-1.99) were increased in those who had >2-day stay (Hudson, 2018). Two research studies associated early nutritional care after risk identification with improved outcomes such as reduced length of stay, reduction in risk of readmissions, and cost of care (Lew, 2016), (Meehan, 2016). An additional study of a learning collaborative of US hospitals demonstrated a statistically significant lower risk of 30-day readmission for malnourished patients who had a documented nutrition care plan (Valladares, 2020). Nutritional status and progress are often not adequately documented in the medical record. It can be difficult to tell when (or if) patients are consuming food and supplements. In addition, nutritional procedures and EHR-triggered care are often lacking in the hospital. Similarly, nutritional care plans and patient issues are poorly communicated to post-acute facilities and PCPs (Corkins, 2014). Additionally, room to improve coordination between registered dietitians and physicians has also been reported (Chambers, 2019; Vest, 2018). Finally, documentation of malnutrition diagnoses has been associated with significant healthcare cost savings per hospital day per patient (Amaral, 2007). REFERENCES: Agarwal E, Ferguson M, Banks M, et al. Malnutrition and poor food intake are associated with prolonged hospital stay, frequent readmissions, and greater in-

hospital mortality: results from the Nutrition Care Day Survey 2010. Clinical nutrition (Edinburgh, Scotland). 2013;32(5):737-745. Allard JP, Keller H, Teterina A, et al. Lower handgrip strength at discharge from acute care hospitals is associated with 30-day readmission: A prospective cohort study. Clinical nutrition (Edinburgh, Scotland). 2016;35(6):1535-1542. Amaral TF, Matos LC, Tavares MM, Subtil A, Martins R, Nazaré M, et al. The economic impact of disease-related malnutrition at hospital admission. Clin Nutr. 2007 Dec;26(6):778–84. Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. ONLINE. August 30, 2018. U.S. Agency for Healthcare Research and Quality. Available: www.hcupus.ahrq.gov/reports.jsp. Chambers R, Bryan J, Jannat-khah D, Russo E, Merriman L, Gupta R. Evaluating Gaps in Care of Malnourished Patients on General Medicine Floors in an Acute Care Setting. Nutr Clin Pract. 2019;34(2):313-318. Corkins MR, Guenter P, Dimaria-ghalili RA, et al. Malnutrition diagnoses in hospitalized patients: United States, 2010. J Parenter Enteral Nutr. 2014;38(2):186-95. Danis K, Kline M, Munson M, et al. Identifying and Managing Malnourished Hospitalized Patients Utilizing the Malnutrition Quality Improvement Initiative: The UPMC Experience. J Acad Nutr Diet. 2019;119(9 Suppl 2):S40-S43. Hiller LD, Shaw RF, Fabri PJ. Difference in Composite End Point of Readmission and Death Between Malnourished and Nonmalnourished Veterans Assessed Using Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Clinical Characteristics. JPEN J Parenter Enteral Nutr. 2017;41(8):1316-1324. Hudson L, Chittams J, Griffith C, Compher C. Malnutrition Identified by Academy of Nutrition and Dietetics/American Society for Parenteral and Enteral Nutrition Is Associated With More 30-Day Readmissions, Greater Hospital Mortality, and Longer Hospital Stays: A Retrospective Analysis of Nutrition Assessment Data in a Major Medical Center. JPEN J Parenter Enteral Nutr. 2018. Khalatbari-Soltani S, Marques-Vidal P. Impact of nutritional risk screening in hospitalized patients on management, outcome and costs: A retrospective study. Clinical nutrition (Edinburgh, Scotland). 2016;35(6):1340-1346. Kruizenga H, van Keeken S, Weijs P, et al. Undernutrition screening survey in 564,063 patients: patients with a positive undernutrition screening score stay in hospital 1.4 d longer. The American journal of clinical nutrition. 2016;103(4):1026-1032. Lew CC, Yandell R, Fraser RJ, Chua AP, Chong MF, Miller M. Association Between Malnutrition and Clinical Outcomes in the Intensive Care Unit: A Systematic Review. JPEN. Journal of parenteral and enteral nutrition. 2016. McCauley SM, Mitchell K & Heap A. The Malnutrition Quality Improvement Initiative: A Multiyear Partnership Transforms Care. J Acad Nutr Diet. 2009;119(9 Suppl 2):S18-S24. Meehan A, Loose C, Bell J, Partridge J, Nelson J, Goates S. Health System Quality Improvement: Impact of Prompt Nutrition Care on Patient Outcomes and Health Care Costs. J Nurs Care Qual. 2016. Nepple K, Tobert C, Valladares A, Mitchell K, Yadrick M. Enhancing identification and management of hospitalized patients who are malnourished: a pilot evaluation of electronic quality improvement measures. J Acad Nutr Diet. 2019;119(9S2):S32-S39. Sauer AC, Goates S, Malone A, et al. Prevalence of Malnutrition Risk and the Impact of Nutrition Risk on Hospital Outcomes: Results From nutrition Day in the U.S. JPEN J Parenter Enteral Nutr. 2019;43(7):918-926. Silver HJ, Pratt KJ, Bruno M, Lynch J, Mitchell K, Mccauley SM. Effectiveness of the Malnutrition Quality Improvement Initiative on Practitioner Malnutrition Knowledge and Screening, Diagnosis, and Timeliness of Malnutrition-Related Care Provided to Older Adults Admitted to a Tertiary Care Facility: A Pilot Study. J Acad Nutr Diet. 2018;118(1):101-109. Sriram K, Sulo S, Vanderbosch G, et al. Nutrition-Focused Quality Improvement Program Results in Significant Readmission and Length of Stay Reductions for Malnourished Surgical Patients. JPEN J Parenter Enteral Nutr. 2018;42(6):1093-1098. Sulo S, Feldstein J, Partridge J, Schwander B, Sriram K, Summerfelt WT. Budget Impact of a Comprehensive Nutrition-Focused Quality Improvement Program for Malnourished Hospitalized Patients. Am Health Drug Benefits. 2017;10(5):262-270. Valladares AF, Kilgore KM, Partridge J, Sulo S, Kerr KW, Mccauley S. How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative.

JPEN J Parenter Enteral Nutr. 2020. Vest MT, Papas MA, Shapero M, Mcgraw P, Capizzi A, Jurkovitz C. Characteristics and Outcomes of Adult Inpatients With Malnutrition. JPEN J Parenter Enteral Nutr. 2018;42(6):1009-1016.

Preliminary Analysis – MUC ID: MUC20-0032 Global Malnutrition Composite Score

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This composite measure addresses an important topic not currently addressed by the measures in the Medicare and Medicaid Promoting Interoperability Programs set, as research (Sauer AC, et al., 2019) has found approximately 1 in 3 hospitalized patients at risk for malnutrition. The developer suggests that implementation of this measure may lead to improvement in outcomes, such as reductions in 30-day readmissions, associated costs, and resource utilization. This measure may be considered to address the high priority Meaningful Measure area to "Promote Effective Communication and Coordination of Care" through the EHR data source and as an eCQM. However, the MAP should consider if this measure advances the goals of the interoperability program.
Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	Yes	This is a composite measure that consists of four measures of malnutrition focused on patients 65 years and older: 1. Screening for malnutrition risk at admission. 2. Completion of a nutrition assessment for patients who screened for risk of malnutrition. 3. Appropriate documentation of malnutrition diagnosis for patients identified with malnutrition. 4. Development of a nutrition care plan for malnourished patients. The developer cites (Valladares, et al., 2020) that patients 65 years and older with a malnutrition diagnosis and nutrition care plan had a 24% lower likelihood of 30-day hospital readmissions compared to those without a care plan. Additionally this research showed Length of Stay (LOS) to be on average 3 days longer for malnourished patients without a nutrition care plan. However, evidence submitted to the Fall 2020 NQF endorsement process by the measure developer notes that screening for malnutrition risk or conducting nutrition assessments were rated Grade E or supported by level IV or V evidence. Additionally, the evidence for providing a nutrition support intervention for patients identified by screening and assessment at risk for malnutrition or malnourished was rated Grade C or supported by at least one level III investigation. MAP should consider if the evidence submitted supports inclusion of the measure in the Medicare and Medicaid Promoting Interoperability Programs for Eligible Hospitals (EHs) or Critical Access Hospitals (CAHs).

Does the measure address a quality challenge?	Yes	Research has shown malnourished patients experience increased risk of in-hospital mortality, higher hospital costs, longer length of stay, and higher likelihood of readmission (Barrett, et al., 2018). It should also be noted that as this measure focuses on patients ages 65 and older, that a recently published study has shown malnourished paients to be older, had a longer length of stay, and were more likely to be readmitted within 30 days(Hudson, et cal., 2018). The developer notes that among hospitals that meet the case minimum of 20 patients and at least 3 reportable measures in 2019, 44.7% of hospitals were in the highest performing Tier 3, 14.9% were in Tier 2, and 40.4% were in Tier 1. This range in performance demonstrate opportunities for improvement.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	The Medicare and Medicaid Promoting Interoperability Programs do not currently include any measures with similar areas of focus or target population. MAP should consider if the measure focus presented by the developer contributes to an understanding of the overall quality and aligned with the program intent.
Can the measure be feasibly reported?	Yes	All components and required data elements within this composite measure are captured within an electronic health record, therefore the measure can be feasibly reported. The required data elements are routinely generated and used during care delivery, as the first component of this composite measure is screening for malnutrition risk at admission. Capturing of the required data can be implemented as has been shown by hospitals that have already put these measure components into operational use.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Yes	The measure is specified and tested at the hospital inpatient acute care facility level of analysis. The Scientific Methods Panel voted in October 2020 to pass this measure. NQF's first evaluation of this measure to be considered for endorsement will occur in 2020-2021, as this measure is be evaluated as part of the Fall 2020 cycle.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	No	Per the measure developer, no unintended consequences have been reported by participating hospitals over 3 years of performance reporting.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • This is an important area of measurement and an important issue for the rural setting. It seems achievable in the rural setting with rural hospitals. Data collection issues: • None Calculation issues: • There was some concern with case volume within the rural setting. Unintended consequences: • No issues identified Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 3.9 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 14 votes 5 – 0 vote
Preliminary Analysis Recommendation	Conditional Support for Rulemaking	Conditional support for rulemaking is recommended pending NQF endorsement of the measure.
Summary: What is the potential value to the program measure set?	[redacted]	This measure addresses a clinical topic area not currently addressed by the measures in the Promoting Interoperability Program (PI) set. Furthermore, this measure may be considered to address the high priority Meaningful Measure area to "Promote Effective Communication and Coordination of Care" through the EHR data source and as an eCQM. MAP should consider if the measure focus presented by the developer contributes to an understanding of the overall quality and aligned with the program intent. The measure was voted on and passed by the Scientific Methods Panel in October 2020 and will be evaluated for endorsement for the first time as part of the Fall 2020 cycle.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	This measure encourages the identification and treatment of malnutrition upon hospital admission for adults age 65 years and older, leading to reduced risk of 30-day readmission, shortened length of stay, reduced risk of in-patient mortality, and lower hospital costs, as compared to malnourished patients that are not screened for risk and treated appropriately. This is a prevalent clinical issue, as recent research has found approximately 1 in 3 hospitalized patients at risk for malnutrition (Sauer AC, et al., 2019). Conditional support for rulemaking is recommended pending NQF endorsement of the measure.

Measure Comments

Author	Submitted Comment
Academy of Nutrition and Dietetics	Data informed decisions can identify and inform staff to prioritize those with malnutrition risk for early nutrition intervention. The publicly available Malnutrition Quality Improvement Initiative (MQii) Toolkit provides practical, interdisciplinary tools and resources to help hospitals implement malnutrition best practices and adopt eCQMs to measure their success in meeting the standards of care. The MQii Toolkit is customizable for individual hospitals and enables the implementation of local QI projects tailored to the unique needs and availability of resources at individual institutions. Use of the MQii Toolkit ensures the adoption of standardized best practice recommendations through the provision of a single, easy to-reference resource. The Toolkit is organized into 10 navigable sections with a complete section dedicated to planning for data collection reducing the burden of data collection and reporting. Additionally, included is a clinical workflow template delineating the steps that should be taken to assess and address malnutrition in patients, along with timeframes for implementing each step.1,2 1Fitall, Eleanor, Jones Pratt, Kelsey, McCauley, Sharon M, Astrauskas, Giedre, Heck, Tracey, Hernandez, Beverly, Johnston, Jill, Silver, Heidi J, Mitchell, Kristi. Improving Malnutrition in Hospitalized Older Adults: The Development, Optimization, and Use of a Supportive Toolkit. Journal of the Academy of Nutrition and Dietetics, Volume 119, Issue 9, S25 - S31. September 2019. https://jandonline.org/article/S2212-2672(19)30503-9/pdf 2Wills, Jennifer. Prioritizing Malnutrition Care Through Discrete eCQM Data Tracking in the Electronic Health Record for an Academic Medical Center. Journal of the Academy of Nutrition and Dietetics, Volume 119, Issue 9, S63, September 2019. https://jandonline.org/article/S2212-2672(19)30584-2/pdf Malnutrition, defined as a nutrition imbalance including under-nutrition and over-nutrition, is a pervasive, but often under-diagnosed, condition in the United States. Malnutrition prevalence is exacerbated among patients who are already ill: chronic diseases such as diabetes, cancer, and gastrointestinal, pulmonary, heart, and chronic kidney disease. Chronic disease treatments can result in changes in nutrient intake and ability to use nutrients, which can lead to malnutrition. The Global Malnutrition Composite Score quality measure is vital to implementation of malnutrition quality improvement and advancing and standardizing nutrition care in hospitalized patients. Lack of evaluation and management can result in negative health and financial outcomes as malnourished adults have been found to utilize more health services with more visits to physicians, hospitals, and emergency rooms. Nutrition interventions have been repeatedly shown to positively impact health status and cost-effective in improving health outcomes among malnourished patients. The Global Malnutrition Composite Score quality measure within the Malnutrition Quality Improvement Initiative (MQii) works to help hospitals and health systems improve malnutrition care and achieve better outcomes. Drawing on the reported experiences of RDNs in MQii Learning Collaborative hospitals and other clinicians it is possible to identify potential hospital practice changes and opportunities for healthcare delivery systems to help promote and better prepare for delivering quality malnutrition care to COVID-19 patients.1 With the SARS-CoV-2 virus triggering the COVID-19 pandemic, the risk for malnutrition and its impacts may be even more pronounced. The Global Malnutrition Composite Score quality measure supports acceleration and dissemination of malnutrition care best practices and thus provides an opportunity to examine how COVID-19 has changed malnutrition identification and care of hospitalized patients. Implications for hospital practice changes in malnutrition care included the need for an interdisciplinary approach, active

	patient and family engagement, early nutrition intervention protocols, flexibility in accomplishing nutrition goals, and leveraging health information technology. 1 Arensberg, Mary Beth, Brunton, Cory, Everett, Wendy, McCauley Sharon M. Feedback from the Frontline and Best Practices: The Challenges and Impact of COVID-19 on Malnutrition Care in Hospitalized Patients. Journal of Nutrition and Diet Supplements, Volume 4, Issue 1, 101, June 2020. http://www.scienceinquest.com/open-access/pdf/jnds/feedback-from-the-frontline-and-best-practices-the-challenges-and-impact-of-covid-19-on-malnutrition-care-in-hospitalized-patients.php
AdvaMed	AdvaMed strongly supports inclusion of the Global Malnutrition Composite Score and has a long history of recommending prioritization of inclusion of a malnutrition-focused measure in the Hospital IQR Program. Early identification of Medicare beneficiaries at risk for malnutrition, prompt nutrition intervention and implementation of an effective care transition plan for patients diagnosed as malnourished or at risk of malnutrition are critical to improve outcomes and patient safety by reducing complications such as infections, falls, and pressure ulcers. AdvaMed believes that these malnutrition-measure components have a strong link to clinical outcomes and are a gap area in current quality reporting systems.
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) appreciates that the measure developer was responsive to previous MAP recommendations on the individual nutrition measures. While three of the components received a recommendation to refine and resubmit once a composite was developed, the MAP did not support including the documentation of a malnutrition diagnosis because it is just a documentation measure. This measure was also not endorsed due to the lack of evidence to support that documentation of a diagnosis was directly linked to improving patient outcomes. In addition the other three measures did not achieve NQF endorsement due to concerns with the underlying evidence, burden of several of the requirements (e.g., documenting within 24 hours of admission, all the components required in the plan of care), and lack of exclusions. The FAH believes that the composite should be endorsed by NQF prior to implementation in the Hospital Inpatient Quality Reporting Program to ensure that these concerns were adequately addressed. As a result, the FAH requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Avalere Health	I appreciate the opportunity to submit my comments in support of NQF #3092, the Global Malnutrition Composite Score. As a clinical nutrition leader at a world-class academic medical center and health system, I have direct experience with implementing the processes of care that are outlined and recommended in the malnutrition composite score.

Our work at UPMC to enhance our malnutrition recognition program with Nutrition focused physical assessment (NFPA) has elevated the focus of malnutrition care across our health system. Increased multidisciplinary collaboration, especially between providers and the clinical nutrition team, in identification and treatment of malnutrition has also been recognized.

As outlined in a peer-reviewed research article published in 2019[1], we specifically tackled improvements in quality of care guided by the malnutrition care process that is addressed by the component measures in the composite with support from the Malnutrition Quality Improvement Initiative (MQii) resources and team. We were able to improve all components of the Global Malnutrition Composite Score with improved timeliness of screening and nutrition assessment. In addition, there was improved care coordination between RNDs and MDs.to ensure patients are properly diagnosed with malnutrition and referred to treatment.

As a result of the hospital-wide efforts to improve risk identification and proper malnutrition diagnosis supported by care coordination, we were able to see a dramatic increase in the number of patients identified with malnutrition and referred to treatment.

- After 5 months of quality improvement, eCQM performance data were collected again (postimplementation of the quality improvement [QI] program) and evaluated to determine if the QI efforts was driving an improvement in clinical practice.
- Performance improved significantly ($P<0.01$) on the malnutrition eCQMs focused on completing a nutrition assessment within 24 hours of identification of malnutrition risk and ensuring documentation of a malnutrition diagnosis if it was identified.
- Other results of the QI efforts included:
  - Increase in the RDNs' own understanding of the importance of their work.
  - Elevation of the RDN role and of the Clinical Nutrition Department relationship with other departments and institution leadership; and
  - An increase in the visibility of nutrition assessments and identification of patient malnutrition across all clinical disciplines.

The implementation of the MQii framework, which includes the important component measures that are a part of this composite measure under review and the MQii Toolkit of quality improvement resources, has been effective in helping identify gaps and improving the care for malnourished patients at clinical facilities. By working collaboratively, the UPMC MQii multidisciplinary team was able to make malnutrition care at their facilities a top priority.

2. Danis K, Kline M, Munson M, et al. Identifying and managing malnourished hospitalized patients utilizing the malnutrition quality improvement initiative: the UPMC experience. J Acad Nutr Diet. 2019;119(9 Suppl 2):S40-S43.

National Hispanic Council on Aging (NHCOA)

On behalf of the National Hispanic Council on Aging (NHCOA), I am pleased to submit comments in support of MUC20-0032, the Global Malnutrition Composite Score.

The National Hispanic Council on Aging is committed to improving the health status of Hispanic older adults, their families, and caregivers. Achieving and maintaining excellent health should be a top priority at any age. Lack of meaningful access to quality health care also contributes to poor health outcomes for Hispanic older adults. Hispanic older adults disproportionately suffer from

afflictions, such as diabetes and HIV with an estimated more than 80% having at least one chronic condition.

Additionally, there is a high prevalence of malnutrition among hospitalized patients, but it frequently goes unrecognized compounding other health conditions. Up to 50% of all patients are at risk for or are malnourished at the time of hospital admission.1 Only 7% of patients are typically diagnosed with malnutrition during their hospital stay.2 Malnutrition has a significant impact on patient outcomes as malnourished hospitalized adults have a 54% higher likelihood of hospital 30-day readmissions than those who are well-nourished.3

Patients with a malnutrition diagnosis and nutrition care plan had 24% reduction in readmission risk vs those without a care plan for outlining intervention and treatment.[4] MUC20-0032 Global Malnutrition Composite Score includes four components that provide a framework of critical steps documenting the timely identification and treatment of patients with malnutrition or at risk for malnutrition.

On behalf of the National Hispanic Council on Aging, we appreciate the opportunity to submit these comments in support of the adoption of MUC20-0032 Global Malnutrition Composite Score.

References:
1. Wells JL and Dumbrell AC. Nutrition and Aging: Assessment and treatment of compromised nutritional status in frail elderly patients. Clin Interv Aging. 2006; 1(1):67-69.
2. Weiss AJ, Fingar KR, Barrett ML, Elixhauser A, Steiner CA, Guenter P, Brown MH. Characteristics of hospital stays involving malnutrition, 2013. HCUP Statistical Brief #210. Rockville, MD: Agency for Healthcare Research and Quality. Available at: http://www.hcup-us.ahrq.gov/reports/statbriefs/sb210-Malnutrition-Hospital-Stays-2013.pdf.
3. Fingar KR, Weiss AJ, Barrett ML, et al. All-cause readmissions following hospital stays for patients with malnutrition, 2013. HCUP Statistical Brief #218. December 2016. Agency for Healthcare Research and Quality, Rockville, MD. https://www.hcup- us.ahrq.gov/reports/statbriefs/sb218-Malnutrition-Readmissions-2013.pdf.
4. Valladares AF, et al. How a Malnutrition Quality Improvement Initiative Furthers Malnutrition Measurement and Care: Results From a Hospital Learning Collaborative. JPEN J Parenter Enteral Nutr. 2020;

American Hospital Association

The AHA disagrees with the MAP's recommendation of Conditional Support and instead suggests a recommendation of Do Not Support. While malnutrition is associated with poorer patient outcomes, this measure does not sufficiently address CMS's Meaningful Measures priorities, and thus should not be considered for inclusion in CMS quality reporting programs.

The developer contends that this composite measure meets the Meaningful Measures priority area of Admissions and Readmissions even though it does not evaluate patient admissions in any way. We struggle to understand how a measure can be labeled an "admission/readmission" measure when it merely has an association or relationship with length of stay or readmissions. Even more puzzling and troubling is that while one can draw a conceptual association between addressing malnutrition and readmission rates, the empirical evidence provided to support that relationship is extremely limited. Indeed, half of the components of the composite (screening for malnutrition and completion of nutrition assessment) did not receive favorable ratings in terms of evidence presented.

Even if there were sufficient evidence supporting the link between nutrition and

	admissions/readmissions, we seriously question whether this measure addresses a high-priority aspect of care quality in inpatient hospitals. It is not a measure of whether patients receive adequate nutrition while in the hospital, but rather a process measure that may – or may not – have a particularly strong linkage to a larger public health issue. Certainly, there are many important aspects of care that one can measure, but the whole point of having a Meaningful Measures framework is to help CMS and the field judge whether even worthy topics should be included in programs given the balance of other important competing priorities. If CMS seeks to create a meaningful, widely applicable, and streamlined measure set for the IQR, we do not believe this measure would "make the cut." The AHA understands why this measure would be under consideration for the Promoting Interoperability Program, as it is informed by simple yes/no data elements in the EHR and would be one of few eCQMs relevant to rural providers. However, it is unclear how this measure would "promote interoperability," as no individual component addresses data sharing or coordination across the continuum. If included in the PIP, providers would likely be able to choose whether to report it, and it is unclear whether the information is captured in structured data fields. These issues would undermine the measure's usefulness.
Federation of American Hospitals	Yes; support for inclusion in the program.
AdvaMed	AdvaMed strongly supports inclusion of the Global Malnutrition Composite Score and has a long history of recommending prioritization of inclusion of a malnutrition-focused measure in the Hospital IQR Program. Early identification of Medicare beneficiaries at risk for malnutrition, prompt nutrition intervention and implementation of an effective care transition plan for patients diagnosed as malnourished or at risk of malnutrition are critical to improve outcomes and patient safety by reducing complications such as infections, falls, and pressure ulcers. AdvaMed believes that these malnutrition-measure components have a strong link to clinical outcomes and are a gap area in current quality reporting systems.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0039
Other Measure Identification Numbers	N/A
Title	Standardized Hospitalization Ratio for Dialysis Facilities (SHR)
Program	End-Stage Renal Disease Quality Incentive Program
Workgroup	MAP Hospital
In what state of development is the measure?	Fully Developed
State of Development Details	N/A
Measure Description	The standardized hospitalization ratio is defined as the ratio of the number of hospital admissions that occur for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. This measure is calculated as a ratio but can also be expressed as a rate. When used for public reporting, the measure calculation will be restricted to facilities with less than 5 patient years at risk in the reporting year. This restriction is required to ensure patients cannot be identified due to small cell size.
Numerator	Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.
Denominator	Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.
Exclusions	N/A
Measure type	Outcome
What is the NQF status of the measure?	Endorsed
NQF ID number	1463
Year of next anticipated NQF CDP endorsement review	2020
Year of most recent NQF Consensus Development Process (CDP) endorsement	2015
Is the measure being submitted exactly as endorsed by NQF?	No
If not exactly as endorsed, describe the nature of the differences	Updates: Prevalent Comorbidity Adjustment: Grouped 210 individual ICD-9 prevalent comorbidities into 90 condition groups, derived from the AHRQ CCS groups. Limited source of prevalent comorbidities to inpatient claims. The switch to using only Medicare in patient claims to identify prevalent comorbidities is due to the lack of Medicare outpatient claims data for the growing Medicare Advantage (MA) patient population. By using the original set of Medicare claims datasets (inpatient, outpatient, hospice, skilled nursing, and home health), MA patient prevalent comorbidities would be systematically biased as they

	would only be populated by Medicare inpatient claims compared to non-MA patient prevalent comorbidities that would be populated by the aforementioned set of Medicare claim sources. Include all time at risk for Medicare Advantage patients, and added a Medicare Advantage indicator for adjustment in the model. Updates to parameterization of existing adjustment factors and re-evaluation of interactions. A patient's time spent in a skilled nursing facility may play a role in increased risk of hospitalization, as nursing home residence is a marker of higher morbidity. UM-KECC has leveraged information from the Medicare Minimum Dataset (MDS) regarding a patient's time spent in a nursing home to create three distinct groups to use in the SHR model. The three groups are those patients who have spent 0, 1-89 (short term), or 90 or more (long term) days in the nursing home in the previous 365 days.
What data sources are used for the measure?	Administrative clinical data; Claims; CROWNWeb
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	Facility
In which setting was this measure tested?	Dialysis facility
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Management of chronic conditions
What secondary meaningful measure area applies to this measure?	Admissions and readmissions to hospitals
What one primary healthcare priority applies to this measure?	Promote effective prevention and treatment of chronic disease
What secondary healthcare priority applies to this measure?	Promote effective communication and coordination of care
What area of specialty best fits the measure?	Nephrology
What is the target	Medicare ESRD

population of the measure?	
Is this measure an eCQM?	No
If eCQM, enter Measure Authoring Tool (MAT) number	No
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Medicare & Medicaid Services
Long-Term Measure Steward (if different)	University of Michigan-KECC
Measure Steward Contact Information	Jesse Roach; Jesse.Roach@CMS.HHS.GOV
Primary Submitter Contact Information	Jennifer Sardone; University of Michigan-KECC; jmsto@med.umich.edu
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	Yes
In what prior year(s) was this measure proposed?	2015
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the	N/A

measure in each year?	
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	Support
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	Measure currently used in a CMS program, but the measure is undergoing substantial change
Range of years(s) this measure has been used by CMS Program(s)	ESRD QIP 2015-2020
What other federal programs are currently using this measure?	End-Stage Renal Disease Quality Incentive Program
Evidence that the measure can be operationalized	N/A
How is the measure expected to be reported to the program?	Claims; CROWNWeb
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A

Rationale for how this measure will add to the CMS program	N/A
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Current Measure
Unintended consequences	N/A
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Hospitalizations are an important indicator of patient morbidity and quality of life. On average, dialysis patients are admitted to the hospital nearly twice a year and spend an average of 11.2 days in the hospital per year [1]. Hospitalizations account for approximately 33% percent of total Medicare expenditures for End-Stage Renal Disease patients [1]. Studies have shown that improved health care delivery and care coordination may help reduce unplanned acute care including hospitalization [1]. Hospitalization rates vary across dialysis facilities even after adjustment for patient characteristics, suggesting that hospitalizations might be influenced by dialysis facility practices. An adjusted facility-level standardized hospitalization ratio, accounting for differences in patients' characteristics, plays an important role in identifying potential problems and helps facilities provide cost-effective quality health care to help limit escalating medical costs. REFERENCE [1] United States Renal Data System. 2018 United States Renal Data System annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2018.

Preliminary Analysis – MUC ID: MUC20-0039 Standardized Hospitalization Ratio for Dialysis Facilities (SHR)

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This fully developed measure is an updated version of an implemented measure in the End-stage Renal Disease Quality Incentive Program (ESRD QIP) under the health care priority area of communication and care coordination. The measure is on the MUC list because of updates to the measure. Updates to the measure are focused on the risk adjustment methods, specifically, inclusion of a prevalent comorbidity adjustment, the addition of Medicare Advantage patients and a Medicare Advantage indicator in the model, updates to parameterization of existing adjustment factors and re-evaluation of interactions, and an indicator for patient's time spent in a skilled nursing facility. The updated version has been reviewed and endorsed by NQF, passed CSAC review in Spring 2020. There are no other competing measures for MUC20-0039 in ESRD QIP.
Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	Yes	The standardized hospitalization ratio is an outcome measure that indicates the ratio of the number of hospital admissions that arise for Medicare ESRD dialysis patients treated at a particular facility to the number of hospitalizations that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. For the recent Spring 2020 review cycle, the developer cited several recent studies that provided effective opportunities for dialysis facilities to reduce hospitalizations that included infection prevention practices, dialysis facility organizational culture, achieving adequate small solute clearance (specifically, the components of the dialysis prescription such as the calcium and sodium concentrations), management of a patient's potassium balance, and maintaining appropriate fluid balance (as it relates to hospitalizations for fluid overload) (NQF Evidence Submission - 1463; page 32-33).
Does the measure address a quality challenge?	Yes	Even after adjustment for patient characteristics, hospitalization rates can vary across dialysis facilities. This suggests that hospitalizations might be influenced by dialysis facility practices. The measure developer cites that dialysis patients are admitted to the hospital frequently, spending an average of 11.2 days in the hospital per year (United States Renal Data System, 2018). These hospitalizations account for one-third of the total Medicare expenditures for ESRD patients (United States Renal Data System, 2018).
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	This facility-level measure is currently implemented in the ESRD QIP program. The previously endorsed measure lacked data on prevalent comorbidities that stemmed from the lack of Medicare outpatient claims data for the Medicare Advantage patient population. Other similar measures include NQF measure #0369: Standardized Mortality Ratio for Dialysis Facilities and NQF measure #2496: Standardized Readmission Ratio (SRR) for Dialysis Facilities, which measure different outcomes using the same target population as MUC20-0039.

Can the measure be feasibly reported?	Yes	The measure uses data that is derived from a national ESRD patient database that is primarily based on CROWNWeb facility-reported clinical and administrative data, the Renal Management Information System (REMIS), the Medicare Enrollment Database (EDB), and Medicare claims data. The database uses multiple electronic datasets. Data on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs), and past-year comorbidity data are obtained from multiple Part A types (inpatient, home health, hospice, skilled nursing facility claims).
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Yes	The measure is specified and tested at the facility-level of analysis in the dialysis facility setting, which is the setting that it is proposed for use. The care setting, level of analysis and population of the measure are the same across the proposed measure, endorsed measure, and program intent. Reliability and validity testing have been conducted, of which both have passed NQF's Spring 2020 Consensus Development Process for endorsement.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?	No	The measure is in current use in the ESRD QIP program, as well as Dialysis Facility Compare. The developer indicates that no negative, unintended issues to the patient have been identified. Commenters have raised issues with whether the outcome of the measure (hospitalizations) should be attributable to the dialysis facility. The concern focused on the lack of exclusions for those hospitalizations that were not related to dialysis treatment or attributable to care provided by the dialysis facility.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input		Relative priority/utility: • A comment was shared that this measure addresses both the cost and quality domains. • Improvements to the measure can now capture Medicare Advantage patients in addition to Fee-for-Service and seems reasonable for rural settings. Data collection issues: • None Calculation issues: • None Unintended consequences: • No issues with current measure Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 3.7 1 – 0 vote 2 – 3 votes 3 – 1 vote 4 – 11 votes 5 – 2 votes
Preliminary Analysis Recommendation	Support for Rulemaking	
Summary: What is the potential value to the program measure set?		This NQF-endorsed measure is currently implemented in the ESRD QIP. The developer reports updates to the risk adjustment method of the measure, which include a prevalent comorbidity adjustment, the addition of Medicare Advantage patients and a Medicare Advantage indicator in the model, updates to parameterization of existing adjustment factors and re-evaluation of interactions, and an indicator for patient's time spent in a skilled nursing facility. These updates have been reviewed by the NQF All-Cause Admissions and Readmissions Standing Committee during the Spring 2020 evaluation cycle, which recommended the measure for continued endorsement. Other similar measures in the ESRD QIP program evaluate different outcomes than MUC20-0039.

Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Hospitalization rates vary across dialysis facilities, even after adjusting for patient characteristics. This suggests that hospitalizations might be influenced by dialysis facility practices. This measure seeks to improve patient outcomes by measuring hospitalization ratios among dialysis facilities. In addition, this measure seeks to promote communication between the dialysis facilities and other care settings to improve care transitions.

Measure Comments

Author	Submitted Comment
Kidney Care Partners (KCP)	Thank you for the opportunity to comment on the Measures Under Consideration (MUCs) for Federal Health Programs prior to the Measure Applications Partnership (MAP) Workgroup and Coordinating Committee meetings. Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We greatly appreciate the MAP undertaking this important work, and we offer the following comments addressing measures proposed for use in the ESRD Quality Incentive Program (QIP). MUC 20-0039—Standardized Hospitalization Ratio (CMS) KCP notes that the Standardized Hospitalization Ratio (SHR) was recently updated and re-endorsed as NQF 1463 in NQF's Admissions/Readmissions Project Spring 2020 Cycle. While CMS makes no reference to NQF 1463 in the materials submitted to the MAP, NQF staff has confirmed that MUC 20-0039 is in fact this most recent iteration of the SHR, reviewed last Spring. As such, our comments reflect the more comprehensive information provided to NQF in the Admissions project. Our concerns with the measure can only be properly conveyed when considering the measure in its entirety; the information submitted to the MAP lacks the specificity required to fully evaluate the measure, and we reiterate our position that it is essential that the full details of the risk model and measure performance (i.e., reliability and validity) be made transparent and available for review during the MAP process, either within the CMS MUC list or via an external link. While KCP remains steadfast in its belief that hospitalization is an important outcome to measure, our longstanding concerns about a number of specification, reliability, and validity issues remain unaddressed for the SHR. • Medicare Advantage (MA) Patients. Data provided by CMS in the NQF Admissions Project indicate that at the end of 2017, 27 percent of dialysis patients had MA coverage (presumably higher now), and this varied widely across states—from about 2 percent in Wyoming to 34 percent in Rhode Island, and more than 44 percent in Puerto Rico. KCP thus concurs with the need to change specifications for the SHR and a number of other CMS measures to accommodate the growing number of MA patients and to avoid disparities in performance due to geography. KCP believes, however, that greater transparency is required by CMS as it updates the relevant measures. One such update is the exclusive use of inpatient claims to identify prevalent comorbidities in the SHR risk model. KCP strongly recommends that CMS perform an analysis of risk model fit under the previous approach and the new in-patient-claims-only approach; currently we are unable to assess whether model fit improved or worsened with the new approach. KCP is particularly concerned that limiting comorbidity data to inpatient claims might skew the model towards a sicker population, and that such a skew might reflect unfavorably on facilities that successfully keep hospitalization rates low. That is, because comorbidity adjustors developed

exclusively from hospitalization data will necessarily underestimate the comorbidity profile of patients in facilities with low hospitalization rates, the "expected" hospitalization and readmission rates calculated for such facilities will be erroneously low, and the facilities' scores will be erroneously high. Only with transparency in these matters can the community assess the impact MA patient mix has on the QIP measures.

• Reliability. We note that a reliability statistic of 0.70 is often considered as "good" reliability, though we recognize the characterization also depends on the analytic method. We thus have concerns about the overall inter-unit reliability (IUR) for the SHR of 0.53-0.59 for 2015-2018—a sizeable decline from the 2010-2013 IUR of 0.70-0.72. This finding indicates that nearly one-half of any facility's score could be attributable to random noise and not signal. KCP believes CMS should implement the measure adjusted to yield a reliable result (reliability statistic of 0.70 or greater), consistent with how NQF bases its evaluation of measures and more generous than the literature.

Moreover, CMS did not provide NQF testing data stratified by facility size for the most recent SHR iteration because it "is not required" by NQF. Yet we note that prior SHR testing results indicated very poor reliability for small facilities (then defined as facilities with fewer than 50 patients for the SHR), with IURs of 0.46-0.54 for 2010-2013 data. Only large facilities (>88 patients) had a reasonable IUR of 0.81-0.82 over the same time period. Given this history and the notable decline in the overall IUR since the measure was last reviewed by NQF, we believe it is disingenuous, at best, not to provide reliability based on facility size merely because NQF "does not require" it. KCP believes penalizing facilities for performance due to random chance is not appropriate and that it is imperative that CMS provide the most recent reliability results stratified by facility size. Absent that information, we submit that the demonstrably unreliable SHR, as currently specified, is particularly unreliable and unsuitable for use in small facilities. KCP believes the measure must specifically require a minimum sample as identified through the developer's empirical testing to prevent small facilities from having scores that are highly subject to random variability.

Finally, to assess more directly the value of SHR in identifying facilities with extreme outcomes, CMS and UM-KECC crafted an additional metric of reliability termed the Profile-IUR (PIUR). Per CMS, "The PIUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. . . . [When] there are outlier providers, even measures with a low IUR can have a relatively high PIUR and can be very useful for identifying extreme providers." The PIUR for the SHR was 0.75-0.85, which CMS interprets as demonstrating that "the SHR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities." Yet we note that NQF's Scientific Methods Panel (SMP) disagrees that the PIUR is an appropriate measure of reliability for any measure used in the ESRD Quality Incentive Program (QIP), which are used to distinguish performance between providers falling in the middle of the curve to determine penalties. The SMP concluded that the IUR is and remains the appropriate measure of reliability for this purpose. KCP concurs with this position.

• Validity. In previous comments to CMS, KCP noted that many of the prevalent comorbidities in the final SHR risk model had p-values significantly greater than 0.05. CMS responded that the large number of clinical factors in the model generates multicollinearity among covariates, likely resulting in some unexpected results in direction of coefficient sign and levels of statistical significance. Nevertheless, KCP remains concerned that this strategy results in a model that will not be generalizable. In the current model, for example, asthma is associated with a higher risk of hospitalization than critical illness myopathy, and 'complete AV block' is protective while 'mood disorders' are harmful. We posit these inexplicable findings are a function of collinearity and coding idiosyncrasy. KCP supports prevalent comorbidity adjustment, but we are concerned that

	the proposed collection of adjusters will be less robust with each year that passes from initial model development. KCP also notes that SHR validity testing yielded a c-statistic of 0.621. We are concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model. • Rates vs Ratios. KCP also again strongly recommends that true risk-standardized rates be used over ratio measures because the latter have relatively wide confidence intervals that can lead to facilities' performance being misclassified. A ratio that is then multiplied by a national median is not a true risk-standardized rate. KCP again thanks you for the opportunity to provide early comments on this important work.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Kidney Care Partners	Thank you for the opportunity to comment on the Measures Under Consideration (MUCs) for use in Federal Health Programs for the Measure Applications Partnership (MAP) 2021 Pre-Rulemaking Cycle. Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We greatly appreciate the MAP undertaking this important work, and we offer the following comments addressing the three measures proposed by the Centers for Medicare and Medicaid Services (CMS) for use in the ESRD Quality Incentive Program (QIP). MUC 20-0039—Standardized Hospitalization Ratio (CMS) KCP does not support MUC 20-0039 and disagrees with the MAP Hospital Workgroup recommendation of "Support." KCP notes that the Standardized Hospitalization Ratio (SHR) was recently updated and re-endorsed as NQF 1463 in NQF's Admissions/Readmissions Project Spring 2020 Cycle; our comments reflect the more comprehensive information provided to NQF within that project, as our concerns with the measure can only be properly conveyed when considering the measure in its entirety. The information submitted to the MAP lacks the specificity required to fully evaluate the measure, and we reiterate our position that it is essential that the full details of the risk model and measure performance (i.e., reliability and validity) be made transparent and available for review during the MAP process, either within the CMS MUC list or via an external link. While KCP remains steadfast in its belief that hospitalization is an important outcome to measure, our concerns about a number of specification, reliability, and validity issues remain unaddressed for the SHR.

• Medicare Advantage (MA) Patients. Data provided by CMS in the NQF Admissions Project indicate that at the end of 2017, 27 percent of dialysis patients had MA coverage (presumably higher now), and this varied widely across states—from about 2 percent in Wyoming to 34 percent in Rhode Island, and more than 44 percent in Puerto Rico. KCP thus concurs with CMS's decision to change specifications for the SHR and a number of other measures to accommodate the growing number of MA patients and to avoid disparities in performance due to geography, but we believe that greater transparency is required by CMS as it updates the relevant measures. One such update is the exclusive use of inpatient claims to identify prevalent comorbidities in the SHR risk model. KCP strongly recommends that CMS perform an analysis of risk model fit under the previous approach and the new in-patient-claims-only approach; currently we are unable to assess whether model fit improved or worsened with the new approach. KCP is particularly concerned that limiting comorbidity data to inpatient claims might skew the model towards a sicker population, and that such a skew might reflect unfavorably on facilities that successfully keep hospitalization rates low. That is, because comorbidity adjustors developed exclusively from hospitalization data will necessarily underestimate the comorbidity profile of patients in facilities with low hospitalization rates, the "expected" hospitalization and readmission rates calculated for such facilities will be erroneously low, and the facilities' scores will be erroneously high. Only with transparency in these matters can the community assess the impact MA patient mix has on the QIP measures.

• Reliability. We note that a reliability statistic of 0.70 is often considered as "good" reliability, though we recognize the characterization also depends on the analytic method. We thus have concerns about the overall inter-unit reliability (IUR) for the SHR of 0.53-0.59 for 2015-2018—a sizeable decline from the 2010-2013 IUR of 0.70-0.72. This finding indicates that nearly one-half of any facility's score could be attributable to random noise and not signal. KCP believes CMS should implement the measure adjusted to yield a reliable result (reliability statistic of 0.70 or greater), consistent with how NQF bases its evaluation of measures and more generous than the literature.

Moreover, CMS did not provide NQF testing data stratified by facility size for the most recent SHR iteration because it "is not required" by NQF. Yet we note that prior SHR testing results indicated very poor reliability for small facilities (then defined as facilities with fewer than 50 patients for the SHR), with IURs of 0.46-0.54 for 2010-2013 data. Only large facilities (>88 patients) had a reasonable IUR of 0.81-0.82 over the same time period. Given this history and the notable decline in the overall IUR since the measure was last reviewed by NQF, we believe it is disingenuous, at best, not to provide reliability based on facility size merely because NQF "does not require" it. KCP believes penalizing facilities for performance due to random chance is not appropriate and that it is imperative that CMS provide the most recent reliability results stratified by facility size. Absent that information, we submit that the demonstrably unreliable SHR, as currently specified, is particularly unreliable and unsuitable for use in small facilities. KCP believes the measure must specifically require a minimum sample as identified through the developer's empirical testing to prevent small facilities from having scores that are highly subject to random variability.

Finally, to assess more directly the value of SHR in identifying facilities with extreme outcomes, CMS and UM-KECC crafted an additional metric of reliability termed the Profile-IUR (PIUR). Per CMS, "The PIUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. . . . [When] there are outlier providers, even measures with a low IUR can have a relatively high PIUR and can be very useful for identifying extreme providers." The PIUR for the SHR was 0.75-0.85, which CMS interprets as demonstrating that "the SHR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities." Yet we note that NQF's Scientific Methods Panel (SMP) disagrees that the PIUR

	is an appropriate measure of reliability for any measure used in the ESRD Quality Incentive Program (QIP), which are used to distinguish performance between providers falling in the middle of the curve to determine penalties. The SMP concluded that the IUR is and remains the appropriate measure of reliability for this purpose. KCP concurs with this position. • Validity. In previous comments to CMS, KCP noted that many of the prevalent comorbidities in the final SHR risk model had p-values significantly greater than 0.05. CMS responded that the large number of clinical factors in the model generates multicollinearity among covariates, likely resulting in some unexpected results in direction of coefficient sign and levels of statistical significance. Nevertheless, KCP remains concerned that this strategy results in a model that will not be generalizable. In the current model, for example, asthma is associated with a higher risk of hospitalization than critical illness myopathy, and 'complete AV block' is protective while 'mood disorders' are harmful. We posit these inexplicable findings are a function of collinearity and coding idiosyncrasy. KCP supports prevalent comorbidity adjustment, but we are concerned that the proposed collection of adjusters will be less robust with each year that passes from initial model development. KCP also notes that SHR validity testing yielded a c-statistic of 0.621. We are concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality. We believe a minimum c-statistic of 0.8 is a more appropriate indicator of the model's goodness of fit and validity to represent meaningful differences among facilities and encourage continuous improvement of the model. • Rates vs Ratios. KCP also again strongly recommends that true risk-standardized rates be used over ratio measures because the latter have relatively wide confidence intervals that can lead to facilities' performance being misclassified. A ratio that is then multiplied by a national median is not a true risk-standardized rate.
Federation of American Hospitals	Yes; support for inclusion in the program.

Characteristic	Submitted Information
MUCID	MUC20-0044
Other Measure Identification Numbers	N/A
Title	MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel
Program	Ambulatory Surgical Center Quality Reporting
Workgroup	MAP Hospital
In what state of development is the measure?	Early Development
State of Development Details	Measure is in Early Development.
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among healthcare personnel (HCP) in IPPS hospitals, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities, ESRD facilities, ambulatory surgical centers, hospital outpatient departments, skilled nursing facilities, and PPS-exempt cancer hospitals.
Numerator	Cumulative number of HCP eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	HCP with contraindications to SARS-CoV-2 vaccination.
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	0000
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as	N/A

endorsed by NQF?	
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	National Healthcare Safety Network
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	None
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Preventative Care
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote Effective Prevention and Treatment of Chronic Disease
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Preventative medicine
What is the target population of the measure?	IRF HCP
Is this measure an eCQM?	No
If eCQM, enter Measure	N/A

Authoring Tool (MAT) number	
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Budnitz, Daniel MD, MPH, CAPT USPHS. Director, Medication Safety Program; Division of Healthcare Quality Promotion; Centers for Disease Control and Prevention. 404-498-0634 dbudnitz@cdc.gov
Primary Submitter Contact Information	Adams, Ariel MSN, RN, AGCNS-BC Division of Chronic and Post Acute-Care (DCPAC), Centers for Medicare and Medicaid Services (CMS). 410.786.8571 Ariel.Adams@cms.hhs.gov
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being	N/A

referenced for each year	
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The data needed to calculate this measure will be collected through the COVID-19 Modules on the NHSN website (https://www.cdc.gov/nhsn/covid19/index.html).
How is the measure expected to be reported to the program?	Web Interface
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Analysis of the score distributions of other HCP vaccination measures in post-acute care, including the Influenza Vaccination among Healthcare Personnel (NQF #0431) measure adopted in the IRF QRP, demonstrate variability in the quality measure scores nationally.
Unintended consequences	IRFs may mistakenly administer the vaccine to HCP with contraindications to administration in an attempt to improve their measure score, despite such HCP being excluded from the measure calculation.
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Health care practice requires close personal exposure to patients, contaminated environment, or infectious material from patients with SARS-CoV-2, putting HCP at high risk of infection and contributing to further spread of COVID-19. (Nguyen et al. 2020) In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and transmission of SARS-CoV-2. Sufficient vaccination coverage of HCP can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in health care facilities, thereby protecting the health of both HCP and patients.

Preliminary Analysis – MUC ID: MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been reviewed by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. The Ambulatory Surgical Center Quality Reporting (ASCQR) Program does not currently have any existing vaccination measures. It should be considered if vaccination coverage for SARS-CoV-2 is of particular importance to the patient population served by Ambulatory Surgical Centers (ASCs).

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The developer provides information from a prospective, observational cohort study illustrating the increased risk of reporting a positive COVID-19 test for front-line healthcare workers (Nguyen et al., 2020). Both the National Academies of Sciences, Engineering, and Medicine and the Centers for Disease Control identify healthcare workers as the highest-priority for SARS-CoV-2 vaccination. The developer states that sufficient vaccination coverage of healthcare personnel (HCP) can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in healthcare facilities, thereby protecting the health of both HCP and patients. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in the ASCQR Program. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronovirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (November 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap. Existing healthcare personnel vaccinations measures demonstrate variation in performance across facilities.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Unclear	This measure provides important information not currently available for this setting or level of analysis. MUC20-0044 is intended for eight federal programs for non-long-term care settings. The developer states that this measure will be submitted using the COVID-19 Modules on the NHSN website. However, recent Federal COVID-19 Guidance for Hospital Reporting states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance. The SARS-CoV-2 measure will be collected for seven job categories: environmental services; nurses; medical assistants and certified nursing assistants; respiratory therapists; pharmacists and pharmacy technicians; physicians and other licensed independent practitioners; and other health care practitioners (HCP; such as students or volunteers). It is unclear what impact the difference data reporting and in data collection categories may have on efficiency or alignment. Alignment considerations will be more important should vaccination against COVID-19 remain a long-term concern. The durability of immunological response is not currently well understood but may weaken quickly, suggesting that COVID-19 vaccination rates may be a long-term measurement issue.

Can the measure be feasibly reported?	Unclear	It is not clear what additional burden this measure would represent or if a different reporting mechanism will be used for the SARS-CoV-2 measure based on recent Federal COVID-19 Guidance for Hospital Reporting that states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use. The measure developer theorizes that ASCs could mistakenly vaccinate individuals with contraindications in an attempt to maximize their score. Individuals with contraindications are excluded from the measure.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply. • Appropriate for the rural community and vaccination coverage of healthcare workers is important. Data collection issues: • None Calculation issues: • None Unintended consequences: • None Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.1 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 12 votes 5 – 3 votes
Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.

Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback to ASCs will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness. Prior to use in the ASCQR Program, this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Do not support
Pfizer	We concur that this vaccination measure would add value, given the current shortages in the healthcare workforce, in ensuring that the personnel are available to provide patient care. In the numerator, the definition of healthcare personnel is broadly defined. In contrast, ACIP defines healthcare personnel to include all paid and unpaid persons as serving in settings who have the potential for direct or indirect exposure to patients or infectious materials. NQF should consider this definition.
American Medical Association	The AMA seeks clarification on whether this measure is for MIPS or IQR. The MUC list listed the measure under IQR. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.
Premier	Premier believes that adoption of this measure is premature. At this time, it unclear if this is a one-time measure for the duration of the ongoing public health emergency or if it will become an annual vaccination. CMS has the authority to request this information outside of quality programs. For example, rates of vaccination could be captured through other COVID-19 reporting mechanisms. Additional clarity is also needed on how health care professionals are defined for purposes of this measure.
America's Essential Hospitals	Members of America's Essential Hospitals understand the value of data and have reported COVID-19 data throughout the pandemic. America's hospitals responded diligently to gather, report, and update data related to COVID-19 and will continue to do so. However, the collection of vaccination data should not be tied to accountability programs, such as the Inpatient Quality Reporting Program. In doing so, CMS indicates these measures could be considered in additional programs, including the overall hospital star ratings or the Value-Based Purchasing Program. There are more appropriate levers for achieving the intended goal of "sufficient vaccination coverage" of health care personnel. In fact, the administration has used other levers, including hospital conditions of participation, to require reporting of COVID-19 data. We do not recommend the vaccination measures for inclusion in CMS programs. We encourage CMS to partner with hospitals to ensure necessary vaccination data and information are voluntarily reported. Additionally, the measure's exclusions and exceptions differ from the other COVID-19 vaccination measures under consideration (namely, MUC20-0045 Vaccination by Clinicians). Exclusions for MUC20-0045 include the vaccine being unavailable and patient refusal. These exclusions are not listed for MUC20-0044 (Vaccination Coverage among Healthcare Personnel).

Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the inclusion of this measure across the multiple quality programs. We would ask that the CDC ensure that the data capture is identical or as close as possible as what is collected for influenza immunization to minimize reporting burden. For example, the FAH recommends that the data be reported across larger groups of employees using the same 4 category scheme for employee classification as influenza (i.e., staff on payroll, licensed independent practitioners, adult students/trainees/volunteers, other contract personnel). In addition, the CDC must continuously revise and update this measure in coordination with other measure developers with similar measures. These revisions should be based on emerging evidence, newly approved vaccinations, and feedback from the field to ensure that each measure reflects the most current knowledge and evidence and can be easily collected and reported. Because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Cerner Corporation	SARS-CoV-2 Vaccination Coverage measure: It is important to collect and analyze COVID-19 vaccination data, but more time should be allowed for better documentation of the vaccine recommendations, schedule, contraindications, etc. before definitive specifications can be determined for the measure tracking and trending that HCP are vaccinated provides additional safety measures to the patients, family members and staff within an ASC. A deeper dive is needed to ensure data tracking of the vaccine is feasible.
The Society for Healthcare Epidemiology of America	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support with Potential for Mitigation. As expressed in a recent policy statement, SHEA believes that all health care personnel (HCP) should be immunized pursuant to CDC and ACIP recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations. However, we support the preliminary recommendation against MUC20-0044's use in any CMS programs – MIPS, IRF QRP, LTCH QRP, SNF QRP, ASCQR, ESRD QIP, Hospital IQR, Hospital OQR, IPR, or PCHQR – at this stage of vaccine deployment. The vaccine's cold-chain storage requirements often limit it to major centers, confounding measurement efforts. Although the measure specifications imply the vaccine should be universally administered, its safety is unproven in certain populations (e.g., pregnant women and immunocompromised patients) and an EUA-authorized vaccine cannot be mandated. Based on our experience, a significant percentage of HCPs are not receiving the vaccine, which could be reflective of vaccine hesitancy or future appointments, among other factors. Furthermore, HIPAA may present a barrier to compiling the data needed to meet the measure. Vaccine

	administration, while logged in state immunization registries, may not be recorded in EHRs and retrievable by providers responsible for the measure.
Federation of American Hospitals	Yes; support for inclusion in the program.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0044
Other Measure Identification Numbers	N/A
Title	MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel
Program	End-Stage Renal Disease QIP
Workgroup	MAP Hospital
In what state of development is the measure?	Early Development
State of Development Details	Measure is in Early Development.
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among healthcare personnel (HCP) in IPPS hospitals, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities, ESRD facilities, ambulatory surgical centers, hospital outpatient departments, skilled nursing facilities, and PPS-exempt cancer hospitals.
Numerator	Cumulative number of HCP eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	HCP with contraindications to SARS-CoV-2 vaccination.
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	0000
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as	N/A

endorsed by NQF?	
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	National Healthcare Safety Network
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	None
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Preventative Care
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote Effective Prevention and Treatment of Chronic Disease
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Preventative medicine
What is the target population of the measure?	IRF HCP
Is this measure an eCQM?	No
If eCQM, enter Measure	N/A

Authoring Tool (MAT) number	
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Budnitz, Daniel MD, MPH, CAPT USPHS. Director, Medication Safety Program; Division of Healthcare Quality Promotion; Centers for Disease Control and Prevention. 404-498-0634 dbudnitz@cdc.gov
Primary Submitter Contact Information	Adams, Ariel MSN, RN, AGCNS-BC Division of Chronic and Post Acute-Care (DCPAC), Centers for Medicare and Medicaid Services (CMS). 410.786.8571 Ariel.Adams@cms.hhs.gov
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being	N/A

referenced for each year	
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The data needed to calculate this measure will be collected through the COVID-19 Modules on the NHSN website (https://www.cdc.gov/nhsn/covid19/index.html).
How is the measure expected to be reported to the program?	Web Interface
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Analysis of the score distributions of other HCP vaccination measures in post-acute care, including the Influenza Vaccination among Healthcare Personnel (NQF #0431) measure adopted in the IRF QRP, demonstrate variability in the quality measure scores nationally.
Unintended consequences	IRFs may mistakenly administer the vaccine to HCP with contraindications to administration in an attempt to improve their measure score, despite such HCP being excluded from the measure calculation.
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Health care practice requires close personal exposure to patients, contaminated environment, or infectious material from patients with SARS-CoV-2, putting HCP at high risk of infection and contributing to further spread of COVID-19. (Nguyen et al. 2020) In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and transmission of SARS-CoV-2. Sufficient vaccination coverage of HCP can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in health care facilities, thereby protecting the health of both HCP and patients.

Preliminary Analysis – MUC ID: MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been review by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. There are no measures in the program set addressing vaccination coverage. Vaccination coverage for SARS-CoV-2 is of particular importance to the vulnerable patient population served by outpatient dialysis facilities.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The developer provides information from a prospective, observational cohort study illustrating the increased risk of reporting a positive COVID-19 test for front-line healthcare workers (Nguyen et al., 2020). Both the National Academies of Sciences, Engineering, and Medicine and the Centers for Disease Control identify healthcare workers as the highest-priority for SARS-CoV-2 vaccination. The developer states that sufficient vaccination coverage of healthcare personnel (HCP) can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in healthcare facilities, thereby protecting the health of both HCP and patients. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in the ESRD QIP. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronovirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (November 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap. Existing healthcare personnel vaccinations measures demonstrate variation in performance across facilities.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	This measure provides important information not currently available for this program, setting or level of analysis. MUC20-0044 is intended for eight federal programs for non-long-term care settings. This measure will be submitted using the COVID-19 Modules on the NHSN website. The SARS-CoV-2 measure will collect data for seven job categories: environmental services; nurses; medical assistants and certified nursing assistants; respiratory therapists; pharmacists and pharmacy technicians; physicians and other licensed independent practitioners; and other health care practitioners (HCP) (such as students or volunteers). Alignment considerations will be more important should vaccination against COVID-19 remain a long-term concern. The durability of immunological response is not currently well understood but may weaken quickly, suggesting that COVID-19 vaccination rates may be a long-term measurement issue.
Can the measure be feasibly reported?	Unclear	This measure will be submitted using the COVID-19 Modules on the NHSN website. Facilities currently participating in ESRD QIP already report other measures. It is not clear what additional burden this measure would represent, as this measure has not been specified sufficiently to indicate the data sources that will be used.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use. The measure developer theorizes that outpatient dialysis facilities could mistakenly vaccinate individuals with contraindications in an attempt to maximize their score. Individuals with contraindications are excluded from the measure.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply. • Appropriate for the rural community and vaccination coverage of healthcare workers is important. • ESRD patients are a high-priority group. Data collection issues: • None Calculation issues: • None Unintended consequences: • None Program gap areas: Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.1 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 12 votes 5 – 3 votes
Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.

Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback to outpatient dialysis facilities will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness. Prior to use in ESRD QIP, this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Do not support
Kidney Care Partners (KCP)	Thank you for the opportunity to comment on the Measures Under Consideration (MUCs) for Federal Health Programs prior to the Measure Applications Partnership (MAP) Workgroup and Coordinating Committee meetings. Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We greatly appreciate the MAP undertaking this important work, and we offer the following comments addressing measures proposed for use in the ESRD Quality Incentive Program (QIP). MUC 20-0044—SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (CDC) SARS-CoV-2 vaccination of patients and healthcare personnel in ESRD facilities is paramount; however, we again note the information provided in the MUC list lacks the specificity required to meaningfully evaluate this new measure at this time. Detailed specifications and information on measure performance (reliability and validity) are both needed during the MAP process to allow stakeholders to determine if the metrics are feasible and will provide an accurate, actionable assessment of this most critical clinical process. And as always, we strongly recommend the measure be submitted to NQF for endorsement, a general pre-requisite for KCP to support inclusion of a measure in any accountability program. KCP again thanks you for the opportunity to provide early comments on this important work.
Pfizer	We concur that this vaccination measure would add value, given the current shortages in the healthcare workforce, in ensuring that the personnel are available to provide patient care. In the numerator, the definition of healthcare personnel is broadly defined. In contrast, ACIP defines healthcare personnel to include all paid and unpaid persons as serving in settings who have the potential for direct or indirect exposure to patients or infectious materials. NQF should consider this definition.
American Medical Association	The AMA seeks clarification on whether this measure is for MIPS or IQR. The MUC list listed the measure under IQR. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.

Premier	Premier believes that adoption of this measure is premature. At this time, it unclear if this is a one-time measure for the duration of the ongoing public health emergency or if it will become an annual vaccination. CMS has the authority to request this information outside of quality programs. For example, rates of vaccination could be captured through other COVID-19 reporting mechanisms. Additional clarity is also needed on how health care professionals are defined for purposes of this measure.
America's Essential Hospitals	Members of America's Essential Hospitals understand the value of data and have reported COVID-19 data throughout the pandemic. America's hospitals responded diligently to gather, report, and update data related to COVID-19 and will continue to do so. However, the collection of vaccination data should not be tied to accountability programs, such as the Inpatient Quality Reporting Program. In doing so, CMS indicates these measures could be considered in additional programs, including the overall hospital star ratings or the Value-Based Purchasing Program. There are more appropriate levers for achieving the intended goal of "sufficient vaccination coverage" of health care personnel. In fact, the administration has used other levers, including hospital conditions of participation, to require reporting of COVID-19 data. We do not recommend the vaccination measures for inclusion in CMS programs. We encourage CMS to partner with hospitals to ensure necessary vaccination data and information are voluntarily reported. Additionally, the measure's exclusions and exceptions differ from the other COVID-19 vaccination measures under consideration (namely, MUC20-0045 Vaccination by Clinicians). Exclusions for MUC20-0045 include the vaccine being unavailable and patient refusal. These exclusions are not listed for MUC20-0044 (Vaccination Coverage among Healthcare Personnel).
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the inclusion of this measure across the multiple quality programs. We would ask that the CDC ensure that the data capture is identical or as close as possible as what is collected for influenza immunization to minimize reporting burden. For example, the FAH recommends that the data be reported across larger groups of employees using the same 4 category scheme for employee classification as influenza (i.e., staff on payroll, licensed independent practitioners, adult students/trainees/volunteers, other contract personnel). In addition, the CDC must continuously revise and update this measure in coordination with other measure developers with similar measures. These revisions should be based on emerging evidence, newly approved vaccinations, and feedback from the field to ensure that each measure reflects the most current knowledge and evidence and can be easily collected and reported. Because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
The Society for Healthcare	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support with Potential for Mitigation. As expressed in a recent policy statement, SHEA believes that all health care personnel

Epidemiology of America	(HCP) should be immunized pursuant to CDC and ACIP recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations. However, we support the preliminary recommendation against MUC20-0044's use in any CMS programs – MIPS, IRF QRP, LTCH QRP, SNF QRP, ASCQR, ESRD QIP, Hospital IQR, Hospital OQR, IPR, or PCHQR – at this stage of vaccine deployment. The vaccine's cold-chain storage requirements often limit it to major centers, confounding measurement efforts. Although the measure specifications imply the vaccine should be universally administered, its safety is unproven in certain populations (e.g., pregnant women and immunocompromised patients) and an EUA-authorized vaccine cannot be mandated. Based on our experience, a significant percentage of HCPs are not receiving the vaccine, which could be reflective of vaccine hesitancy or future appointments, among other factors. Furthermore, HIPAA may present a barrier to compiling the data needed to meet the measure. Vaccine administration, while logged in state immunization registries, may not be recorded in EHRs and retrievable by providers responsible for the measure.
Kidney Care Partners	MUC 20-0044—SARS-CoV-2 Vaccination Coverage among Healthcare Personnel (CDC) KCP agrees that SARS-CoV-2 vaccination in ESRD facilities is paramount. However, while every KCP Member Organization is committed to and has prioritized COVID vaccination for both patients and healthcare personnel, we do not believe a performance metric will effectively drive this clinical process at this early juncture; we thus do not support MUC 20-0044 for use in the ESRD QIP. We agree with the Hospital Workgroup that the information provided to the MAP lacks the specificity required to meaningfully evaluate the proposed measure, but more, we believe the introduction of the measure is extremely premature. We note the very specific details needed to build a meaningful, valid, and reliable performance measure (e.g., appropriate exclusions, contraindications, dosing schedules, and vaccination intervals) will not be fully fleshed out in the foreseeable future. We fear a rush to develop this fledgling concept while our understanding of SARS-CoV-2 is still rapidly evolving will result in an unsound performance measure that will unnecessarily and unintentionally complicate this most critical clinical process during this unprecedented public health emergency. As a matter of process, we also reiterate our longstanding position that it is critical that detailed specifications and information on measure performance (reliability and validity) be provided during the MAP process to allow stakeholders to determine if metrics are feasible and will provide an accurate, actionable assessment of care. It is also critical to note that the SARS-CoV-2 vaccines are authorized for use under an FDA Emergency Use Authorization (EUA). As EUA documents are viewed as recommendations and do not establish legally enforceable processes of care, any performance measure assessing COVID vaccination would be wholly inappropriate for use in the ERSD QIP, a value-based purchasing program which requires providers to report and meet or exceed performance standards to avoid payment penalties. KCP thus believes that even when fully specified and tested, MUC 20-0044 cannot ethically be used in the QIP until the COVID-19 public health emergency ends and/or the vaccines have received full approval from the FDA. When the above conditions have been met, we support the Hospital Workgroup's recommendation that the measure be submitted to NQF for endorsement, a general pre-requisite for KCP to support inclusion of a measure in any accountability program.

Federation of American Hospitals	Yes; support for inclusion in the program.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0044
Other Measure Identification Numbers	N/A
Title	MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel
Program	Hospital Outpatient Quality Reporting
Workgroup	MAP Hospital
In what state of development is the measure?	Early Development
State of Development Details	Measure is in Early Development.
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among healthcare personnel (HCP) in IPPS hospitals, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities, ESRD facilities, ambulatory surgical centers, hospital outpatient departments, skilled nursing facilities, and PPS-exempt cancer hospitals.
Numerator	Cumulative number of HCP eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	HCP with contraindications to SARS-CoV-2 vaccination.
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	0000
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted	N/A

exactly as endorsed by NQF?	
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	National Healthcare Safety Network
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	None
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Preventative Care
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote Effective Prevention and Treatment of Chronic Disease
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Preventative medicine
What is the target population of the measure?	IRF HCP
Is this measure an eCQM?	No

If eCQM, enter Measure Authoring Tool (MAT) number	N/A
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Budnitz, Daniel MD, MPH, CAPT USPHS. Director, Medication Safety Program; Division of Healthcare Quality Promotion; Centers for Disease Control and Prevention. 404-498-0634 dbudnitz@cdc.gov
Primary Submitter Contact Information	Adams, Ariel MSN, RN, AGCNS-BC Division of Chronic and Post Acute-Care (DCPAC), Centers for Medicare and Medicaid Services (CMS). 410.786.8571 Ariel.Adams@cms.hhs.gov
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A

NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The data needed to calculate this measure will be collected through the COVID-19 Modules on the NHSN website (https://www.cdc.gov/nhsn/covid19/index.html).
How is the measure expected to be reported to the program?	Web Interface
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this	N/A

measure will add to the CMS program	
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Analysis of the score distributions of other HCP vaccination measures in post-acute care, including the Influenza Vaccination among Healthcare Personnel (NQF #0431) measure adopted in the IRF QRP, demonstrate variability in the quality measure scores nationally.
Unintended consequences	IRFs may mistakenly administer the vaccine to HCP with contraindications to administration in an attempt to improve their measure score, despite such HCP being excluded from the measure calculation.
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Health care practice requires close personal exposure to patients, contaminated environment, or infectious material from patients with SARS-CoV-2, putting HCP at high risk of infection and contributing to further spread of COVID-19. (Nguyen et al. 2020) In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and transmission of SARS-CoV-2. Sufficient vaccination coverage of HCP can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in health care facilities, thereby protecting the health of both HCP and patients.

Preliminary Analysis – MUC ID: MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been review by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. The Hospital Outpatient Quality Reporting Program (Hospital OQR Program) does not include any measures of vaccination for healthcare personnel (HCPs) or patients.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The developer provides information from a prospective, observational cohort study illustrating the increased risk of reporting a positive COVID-19 test for front-line healthcare workers (Nguyen et al., 2020). Both the National Academies of Sciences, Engineering, and Medicine and the Centers for Disease Control identify healthcare workers as the highest-priority for SARS-CoV-2 vaccination. The developer states that sufficient vaccination coverage of healthcare personnel (HCP) can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in healthcare facilities, thereby protecting the health of both HCP and patients. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in the Hospital OQR Program. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronovirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (November 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap. Existing healthcare personnel vaccinations measures demonstrate variation in performance across facilities.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Unclear	This measure provides important information not currently available for this setting or level of analysis. MUC20-0044 is intended for eight federal programs for non-long-term care settings. The developer indicates that this measure will be submitted using the COVID-19 Modules on the NHSN website. However, recent Federal COVID-19 Guidance for Hospital Reporting states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance. The SARS-CoV-2 measure will be collected for seven job categories: environmental services; nurses; medical assistants and certified nursing assistants; respiratory therapists; pharmacists and pharmacy technicians; physicians and other licensed independent practitioners; and other health care practitioners (HCP) (such as students or volunteers) not included in the previously listed categories. It is unclear what impact the difference in data reporting and in data collection categories may have on efficiency or alignment. Alignment considerations will be more important should vaccination against COVID-19 remain a long-term concern. The durability of immunological response is not currently well understood but may weaken quickly, suggesting that COVID-19 vaccination rates may be a long-term measurement issue.
Can the measure be feasibly reported?	Unclear	Facilities currently participating in HOQF program already report other measures. It is not clear what additional burden this measure would represent or if a different reporting mechanism will be used for the SARS-CoV-2 measure based on recent Federal COVID-19 Guidance for Hospital Reporting that states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use. The measure developer theorizes that individuals with contraindications could be mistakenly vaccinated in an attempt to maximize their score. Individuals with contraindications are excluded from the measure.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	
Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply. • Appropriate for the rural community and vaccination coverage of healthcare workers is important. Data collection issues: • None Calculation issues: • None Unintended consequences: • None Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.1 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 12 votes 5 – 3 votes

Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness. Prior to use in the Hospital OQR Program, this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Do not support
Pfizer	We concur that this vaccination measure would add value, given the current shortages in the healthcare workforce, in ensuring that the personnel are available to provide patient care. In the numerator, the definition of healthcare personnel is broadly defined. In contrast, ACIP defines healthcare personnel to include all paid and unpaid persons as serving in settings who have the potential for direct or indirect exposure to patients or infectious materials. NQF should consider this definition.
American Medical Association	The AMA seeks clarification on whether this measure is for MIPS or IQR. The MUC list listed the measure under IQR. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.
Premier	Premier believes that adoption of this measure is premature. At this time, it unclear if this is a one-time measure for the duration of the ongoing public health emergency or if it will become an annual vaccination. CMS has the authority to request this information outside of quality programs. For example, rates of vaccination could be captured through other COVID-19 reporting mechanisms. Additional clarity is also needed on how health care professionals are defined for purposes of this measure.

America's Essential Hospitals	Members of America's Essential Hospitals understand the value of data and have reported COVID-19 data throughout the pandemic. America's hospitals responded diligently to gather, report, and update data related to COVID-19 and will continue to do so. However, the collection of vaccination data should not be tied to accountability programs, such as the Inpatient Quality Reporting Program. In doing so, CMS indicates these measures could be considered in additional programs, including the overall hospital star ratings or the Value-Based Purchasing Program. There are more appropriate levers for achieving the intended goal of "sufficient vaccination coverage" of health care personnel. In fact, the administration has used other levers, including hospital conditions of participation, to require reporting of COVID-19 data. We do not recommend the vaccination measures for inclusion in CMS programs. We encourage CMS to partner with hospitals to ensure necessary vaccination data and information are voluntarily reported. Additionally, the measure's exclusions and exceptions differ from the other COVID-19 vaccination measures under consideration (namely, MUC20-0045 Vaccination by Clinicians). Exclusions for MUC20-0045 include the vaccine being unavailable and patient refusal. These exclusions are not listed for MUC20-0044 (Vaccination Coverage among Healthcare Personnel).
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the inclusion of this measure across the multiple quality programs. We would ask that the CDC ensure that the data capture is identical or as close as possible as what is collected for influenza immunization to minimize reporting burden. For example, the FAH recommends that the data be reported across larger groups of employees using the same 4 category scheme for employee classification as influenza (i.e., staff on payroll, licensed independent practitioners, adult students/trainees/volunteers, other contract personnel). In addition, the CDC must continuously revise and update this measure in coordination with other measure developers with similar measures. These revisions should be based on emerging evidence, newly approved vaccinations, and feedback from the field to ensure that each measure reflects the most current knowledge and evidence and can be easily collected and reported. Because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
The Society for Healthcare Epidemiology of America	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support with Potential for Mitigation. As expressed in a recent policy statement, SHEA believes that all health care personnel (HCP) should be immunized pursuant to CDC and ACIP recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations. However, we support the preliminary recommendation against MUC20-0044's use in any CMS

	programs – MIPS, IRF QRP, LTCH QRP, SNF QRP, ASCQR, ESRD QIP, Hospital IQR, Hospital OQR, IPR, or PCHQR – at this stage of vaccine deployment. The vaccine's cold-chain storage requirements often limit it to major centers, confounding measurement efforts. Although the measure specifications imply the vaccine should be universally administered, its safety is unproven in certain populations (e.g., pregnant women and immunocompromised patients) and an EUA-authorized vaccine cannot be mandated. Based on our experience, a significant percentage of HCPs are not receiving the vaccine, which could be reflective of vaccine hesitancy or future appointments, among other factors. Furthermore, HIPAA may present a barrier to compiling the data needed to meet the measure. Vaccine administration, while logged in state immunization registries, may not be recorded in EHRs and retrievable by providers responsible for the measure.
Federation of American Hospitals	Yes; support for inclusion in the program.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0044
Other Measure Identification Numbers	N/A
Title	MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel
Program	Hospital Inpatient Quality Reporting Program
Workgroup	MAP Hospital
In what state of development is the measure?	Early Development
State of Development Details	Measure is in Early Development.
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among healthcare personnel (HCP) in IPPS hospitals, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities, ESRD facilities, ambulatory surgical centers, hospital outpatient departments, skilled nursing facilities, and PPS-exempt cancer hospitals.
Numerator	Cumulative number of HCP eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	HCP with contraindications to SARS-CoV-2 vaccination.
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	0000
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as	N/A

endorsed by NQF?	
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	National Healthcare Safety Network
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	None
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Preventative Care
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote Effective Prevention and Treatment of Chronic Disease
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Preventative medicine
What is the target population of the measure?	IRF HCP
Is this measure an eCQM?	No
If eCQM, enter Measure	N/A

Authoring Tool (MAT) number	
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Budnitz, Daniel MD, MPH, CAPT USPHS. Director, Medication Safety Program; Division of Healthcare Quality Promotion; Centers for Disease Control and Prevention. 404-498-0634 dbudnitz@cdc.gov
Primary Submitter Contact Information	Adams, Ariel MSN, RN, AGCNS-BC Division of Chronic and Post Acute-Care (DCPAC), Centers for Medicare and Medicaid Services (CMS). 410.786.8571 Ariel.Adams@cms.hhs.gov
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being	N/A

referenced for each year	
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The data needed to calculate this measure will be collected through the COVID-19 Modules on the NHSN website (https://www.cdc.gov/nhsn/covid19/index.html).
How is the measure expected to be reported to the program?	Web Interface
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Analysis of the score distributions of other HCP vaccination measures in post-acute care, including the Influenza Vaccination among Healthcare Personnel (NQF #0431) measure adopted in the IRF QRP, demonstrate variability in the quality measure scores nationally.
Unintended consequences	IRFs may mistakenly administer the vaccine to HCP with contraindications to administration in an attempt to improve their measure score, despite such HCP being excluded from the measure calculation.
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Health care practice requires close personal exposure to patients, contaminated environment, or infectious material from patients with SARS-CoV-2, putting HCP at high risk of infection and contributing to further spread of COVID-19. (Nguyen et al. 2020) In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and transmission of SARS-CoV-2. Sufficient vaccination coverage of HCP can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in health care facilities, thereby protecting the health of both HCP and patients.

Preliminary Analysis – MUC ID: MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been reviewed by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. There is an existing measure in the Hospital Inpatient Quality Reporting (Hospital IQR Program) program set addressing influenza vaccination coverage (NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel), but no measures addressing SARS-CoV-2 vaccination. Vaccination coverage for SARS-CoV-2 is of particular importance to reduce SARS-CoV-2-related morbidity and mortality among HCP and patients within the inpatient hospital setting.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The developer provides information from a prospective, observational cohort study illustrating the increased risk of reporting a positive COVID-19 test for front-line healthcare workers (Nguyen et al., 2020). Both the National Academies of Sciences, Engineering, and Medicine and the Centers for Disease Control identify healthcare workers as the highest-priority for SARS-CoV-2 vaccination. The developer states that sufficient vaccination coverage of healthcare personnel (HCP) can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in healthcare facilities, thereby protecting the health of both HCP and patients. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in the Hospital IQR Program. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronovirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (November 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap. Existing healthcare personnel vaccinations measures demonstrate variation in performance across facilities.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Unclear	This measure provides important information not currently available for this setting or level of analysis. MUC20-0044 is intended for eight federal programs for non-long-term care settings. The developer indicates that this measure will be submitted using the COVID-19 Modules on the NHSN website. However, recent Federal COVID-19 Guidance for Hospital Reporting states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance. The NHSN is the same submission method used for the existing influenza vaccination measure (NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel). The two measures have different categories for data collection, with the influenza measure collected for three populations: employees, independent licensed practitioners, and adult/student trainees and volunteers. The SARS-CoV-2 measure will be collected for seven job categories: environmental services; nurses; medical assistants and certified nursing assistants; respiratory therapists; pharmacists and pharmacy technicians; physicians and other licensed independent practitioners; and other health care practitioners (HCP) (such as students or volunteers) not included in the previously listed categories. It is unclear what impact the difference in data reporting and in data collection categories may have on efficiency or alignment. Alignment considerations will be more important should vaccination against COVID-19 remain a long-term concern. The durability of immunological response is not currently well understood but may weaken quickly, suggesting that COVID-19 vaccination rates may be a long-term measurement issue.
Can the measure be feasibly reported?	Unclear	Facilities currently participating in the Hospital IQR Program already report other measures, including those capturing healthcare personnel vaccination with other vaccines, using NSHN. It is not clear what additional burden this measure would represent or if a different reporting mechanism will be used for the SARS-CoV-2 measure based on recent Federal COVID-19 Guidance for Hospital Reporting that states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use. The measure developer theorizes that individuals with contraindications could be mistakenly vaccinated in an attempt to maximize their score. Individuals with contraindications are excluded from the measure.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	
Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply by that time. • Appropriate for the rural community and vaccination coverage of healthcare workers is important. Data collection issues: • None Calculation issues: • None Unintended consequences: • None Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.1 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 12 votes 5 – 3 votes

Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback to facilities will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness. Prior to use in the Hospital IQR Program this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Do not support
Pfizer	We concur that this vaccination measure would add value, given the current shortages in the healthcare workforce, in ensuring that the personnel are available to provide patient care. In the numerator, the definition of healthcare personnel is broadly defined. In contrast, ACIP defines healthcare personnel to include all paid and unpaid persons as serving in settings who have the potential for direct or indirect exposure to patients or infectious materials. NQF should consider this definition.
American Medical Association	The AMA seeks clarification on whether this measure is for MIPS or IQR. The MUC list listed the measure under IQR. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.
Premier	Premier believes that adoption of this measure is premature. At this time, it unclear if this is a one-time measure for the duration of the ongoing public health emergency or if it will become an annual vaccination. CMS has the authority to request this information outside of quality programs. For example, rates of vaccination could be captured through other COVID-19 reporting mechanisms. Additional clarity is also needed on how health care professionals are defined for purposes of this measure.

America's Essential Hospitals	Members of America's Essential Hospitals understand the value of data and have reported COVID-19 data throughout the pandemic. America's hospitals responded diligently to gather, report, and update data related to COVID-19 and will continue to do so. However, the collection of vaccination data should not be tied to accountability programs, such as the Inpatient Quality Reporting Program. In doing so, CMS indicates these measures could be considered in additional programs, including the overall hospital star ratings or the Value-Based Purchasing Program. There are more appropriate levers for achieving the intended goal of "sufficient vaccination coverage" of health care personnel. In fact, the administration has used other levers, including hospital conditions of participation, to require reporting of COVID-19 data. We do not recommend the vaccination measures for inclusion in CMS programs. We encourage CMS to partner with hospitals to ensure necessary vaccination data and information are voluntarily reported. Additionally, the measure's exclusions and exceptions differ from the other COVID-19 vaccination measures under consideration (namely, MUC20-0045 Vaccination by Clinicians). Exclusions for MUC20-0045 include the vaccine being unavailable and patient refusal. These exclusions are not listed for MUC20-0044 (Vaccination Coverage among Healthcare Personnel).
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the inclusion of this measure across the multiple quality programs. We would ask that the CDC ensure that the data capture is identical or as close as possible as what is collected for influenza immunization to minimize reporting burden. For example, the FAH recommends that the data be reported across larger groups of employees using the same 4 category scheme for employee classification as influenza (i.e., staff on payroll, licensed independent practitioners, adult students/trainees/volunteers, other contract personnel). In addition, the CDC must continuously revise and update this measure in coordination with other measure developers with similar measures. These revisions should be based on emerging evidence, newly approved vaccinations, and feedback from the field to ensure that each measure reflects the most current knowledge and evidence and can be easily collected and reported. Because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
The Society for Healthcare Epidemiology of America	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support with Potential for Mitigation. As expressed in a recent policy statement, SHEA believes that all health care personnel (HCP) should be immunized pursuant to CDC and ACIP recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations. However, we support the preliminary recommendation against MUC20-0044's use in any CMS

	programs – MIPS, IRF QRP, LTCH QRP, SNF QRP, ASCQR, ESRD QIP, Hospital IQR, Hospital OQR, IPR, or PCHQR – at this stage of vaccine deployment. The vaccine's cold-chain storage requirements often limit it to major centers, confounding measurement efforts. Although the measure specifications imply the vaccine should be universally administered, its safety is unproven in certain populations (e.g., pregnant women and immunocompromised patients) and an EUA-authorized vaccine cannot be mandated. Based on our experience, a significant percentage of HCPs are not receiving the vaccine, which could be reflective of vaccine hesitancy or future appointments, among other factors. Furthermore, HIPAA may present a barrier to compiling the data needed to meet the measure. Vaccine administration, while logged in state immunization registries, may not be recorded in EHRs and retrievable by providers responsible for the measure.
Association of American Medical Colleges (AAMC)	The Hospital MAP did not support the COVID-19 vaccination process measure (MUC2020-0044), with potential for mitigation. The three areas for mitigation are that prior to implementation the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The AAMC supports the efforts to advance measurement in response to the national pandemic but does not support inclusion of a measure that has not been fully specified and is currently under development. Furthermore, the AAMC is concerned that this measure is premature when no vaccine is fully approved (beyond an emergency use authorization) by the Food and Drug Administration (FDA) nor is widely available. The AAMC agrees with the MAP's recommendation.
American Hospital Association	The AHA appreciates CMS's rationale behind introducing this unspecified measure and understands the urgency of addressing COVID-19 vaccination rates among healthcare personnel. However, we urge extreme caution in implementing this measure in the future as its use could have negative unintended consequences and might not be a useful tool in encouraging vaccination. We agree with the MAP Workgroup's recommendation of Do Not Support with Potential For Mitigation, mitigating factors including well documented evidence of provider influence on vaccination rates and finalized specifications coupled with testing and endorsement. While it stands to reason that this measure would operate similarly to the NHSN flu vaccination of healthcare personnel measure, we simply do not have enough information or experience with the COVID vaccine and its distribution to make any assumptions. Looking ahead, public reporting of this measure will be challenging even if measure is fully tested prior to its implementation because vaccination implementation is likely to undergo several changes as new vaccines enter the market (among other updates). This measure may also carry unintended consequences. As we understand it, one of CMS's goals in including this vaccination measure is to align is quality measurement programs with the vitally important efforts around COVID-19 pandemic response. To be sure, vaccination is a critical part of that response. Yet, it is important to note that vaccination is one among many strategies hospitals have been using to increase the safety of healthcare personnel. The inclusion of any measure in a public reporting program means it will garner significant attention and resources, and so we urge CMS to ensure the inclusion of the measure in the program does not detract from other efforts to keep personnel and patients safe during the pandemic. . In addition, the reporting burden associated with this measure may be high depending on how it interacts with the flu vaccination measure. The latter is specified around a "season," providing a specific window with which to define the population; it is unclear whether the COVID vaccination measure would have a similar "season" or what the reporting frequency would be. It would be burdensome if the two measures

	were not aligned in timeline or data capture approach. The measure appears further misaligned from the other COVID vaccination measures under consideration this cycle in that it asks about healthcare personnel who received a complete course of the vaccination, whereas the MIPS patient vaccination measure asks about a single dose; similarly, the exclusions only include contraindications without allowances for logistical concerns like availability. Again, we understand that these measures are not fully specified and CMS hopes to have more definitive information by the time the measures are proposed for inclusion in its quality programs. However, it is important to strive for alignment in measurement across the continuum of care so that all healthcare personnel working with comparable tools.
Federation of American Hospitals	Yes; support for inclusion in the program.
American Heart Association/ American Stroke Association	The AHA strongly supports CoV-2 vaccination efforts, however, we are uncertain that a quality measure is the most effective method to promote widespread vaccination at this point. Given the uncertainties around supply, in particular, which are likely to persist for some time, it is questionable whether every facility in every part of the U.S. can achieve this. At a minimum, the measure should include a system reason exception to allow for supply issues and the limited control an institution may have over this.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0044
Other Measure Identification Numbers	N/A
Title	MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel
Program	Inpatient Psychiatric Facility Quality Reporting Program
Workgroup	MAP Hospital
In what state of development is the measure?	Early Development
State of Development Details	Measure is in Early Development.
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among healthcare personnel (HCP) in IPPS hospitals, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities, ESRD facilities, ambulatory surgical centers, hospital outpatient departments, skilled nursing facilities, and PPS-exempt cancer hospitals.
Numerator	Cumulative number of HCP eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	HCP with contraindications to SARS-CoV-2 vaccination.
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	0000
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as	N/A

endorsed by NQF?	
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	National Healthcare Safety Network
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	None
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Preventative Care
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote Effective Prevention and Treatment of Chronic Disease
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Preventative medicine
What is the target population of the measure?	IRF HCP
Is this measure an eCQM?	No
If eCQM, enter Measure	N/A

Authoring Tool (MAT) number	
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Budnitz, Daniel MD, MPH, CAPT USPHS. Director, Medication Safety Program; Division of Healthcare Quality Promotion; Centers for Disease Control and Prevention. 404-498-0634 dbudnitz@cdc.gov
Primary Submitter Contact Information	Adams, Ariel MSN, RN, AGCNS-BC Division of Chronic and Post Acute-Care (DCPAC), Centers for Medicare and Medicaid Services (CMS). 410.786.8571 Ariel.Adams@cms.hhs.gov
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being	N/A

referenced for each year	
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The data needed to calculate this measure will be collected through the COVID-19 Modules on the NHSN website (https://www.cdc.gov/nhsn/covid19/index.html).
How is the measure expected to be reported to the program?	Web Interface
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Analysis of the score distributions of other HCP vaccination measures in post-acute care, including the Influenza Vaccination among Healthcare Personnel (NQF #0431) measure adopted in the IRF QRP, demonstrate variability in the quality measure scores nationally.
Unintended consequences	IRFs may mistakenly administer the vaccine to HCP with contraindications to administration in an attempt to improve their measure score, despite such HCP being excluded from the measure calculation.
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Health care practice requires close personal exposure to patients, contaminated environment, or infectious material from patients with SARS-CoV-2, putting HCP at high risk of infection and contributing to further spread of COVID-19. (Nguyen et al. 2020) In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and transmission of SARS-CoV-2. Sufficient vaccination coverage of HCP can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in health care facilities, thereby protecting the health of both HCP and patients.

Preliminary Analysis – MUC ID: MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been reviewed by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. There is a measure in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program set addressing influenza vaccination coverage (NQF #1659 Influenza Immunization), but no measures addressing SARS-CoV-2 vaccination. Vaccination coverage for SARS-CoV-2 is of particular importance to reduce SARS-CoV-2-related morbidity and mortality among patients and healthcare personnel within inpatient psychiatric facilities (IPFs).

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The developer provides information from a prospective, observational cohort study illustrating the increased risk of reporting a positive COVID-19 test for front-line healthcare workers (Nguyen et al., 2020). Both the National Academies of Sciences, Engineering, and Medicine and the Centers for Disease Control identify healthcare workers as the highest-priority for SARS-CoV-2 vaccination. The developer states that sufficient vaccination coverage of healthcare personnel (HCP) can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in healthcare facilities, thereby protecting the health of both HCP and patients. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in the IPFQR Program. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronovirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (November 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap. Existing healthcare personnel vaccinations measures demonstrate variation in performance across facilities.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Unclear	This measure provides important information not currently available for this setting or level of analysis. MUC20-0044 is intended for eight federal programs for non-long-term care settings. The developer states that this measure will be submitted using the COVID-19 Modules on the NHSN website. However, recent Federal COVID-19 Guidance for Hospital Reporting states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance. The SARS-CoV-2 measure will be collected for seven job categories: environmental services; nurses; medical assistants and certified nursing assistants; respiratory therapists; pharmacists and pharmacy technicians; physicians and other licensed independent practitioners; and other health care practitioners (HCP; such as students or volunteers). It is unclear what impact the difference in data reporting and in data collection categories may have on efficiency or alignment. Alignment considerations will be more important should vaccination against COVID-19 remain a long-term concern. The durability of immunological response is not currently well understood but may weaken quickly, suggesting that COVID-19 vaccination rates may be a long-term measurement issue.

Can the measure be feasibly reported?	Unclear	Facilities currently participating in IPFQR program already report other measures. It is not clear what additional burden this measure would represent or if a different reporting mechanism will be used for the SARS-CoV-2 measure based on recent Federal COVID-19 Guidance for Hospital Reporting that states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.
If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use. The measure developer theorizes that IPFs could mistakenly vaccinate individuals with contraindications in an attempt to maximize their score. Individuals with contraindications are excluded from the measure.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	

Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply by that time. • Appropriate for the rural community and vaccination coverage of healthcare workers is important. Data collection issues: • None Calculation issues: • None Unintended consequences: • None Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.1 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 12 votes 5 – 3 votes
Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.

Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback to IPFs will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness. Prior to use in the ASCQR Program, this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Do not support
Pfizer	We concur that this vaccination measure would add value, given the current shortages in the healthcare workforce, in ensuring that the personnel are available to provide patient care. In the numerator, the definition of healthcare personnel is broadly defined. In contrast, ACIP defines healthcare personnel to include all paid and unpaid persons as serving in settings who have the potential for direct or indirect exposure to patients or infectious materials. NQF should consider this definition.
American Medical Association	The AMA seeks clarification on whether this measure is for MIPS or IQR. The MUC list listed the measure under IQR. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.
Premier	Premier believes that adoption of this measure is premature. At this time, it unclear if this is a one-time measure for the duration of the ongoing public health emergency or if it will become an annual vaccination. CMS has the authority to request this information outside of quality programs. For example, rates of vaccination could be captured through other COVID-19 reporting mechanisms. Additional clarity is also needed on how health care professionals are defined for purposes of this measure.
America's Essential Hospitals	Members of America's Essential Hospitals understand the value of data and have reported COVID-19 data throughout the pandemic. America's hospitals responded diligently to gather, report, and update data related to COVID-19 and will continue to do so. However, the collection of vaccination data should not be tied to accountability programs, such as the Inpatient Quality Reporting Program. In doing so, CMS indicates these measures could be considered in additional programs, including the overall hospital star ratings or the Value-Based Purchasing Program. There are more appropriate levers for achieving the intended goal of "sufficient vaccination coverage" of health care personnel. In fact, the administration has used other levers, including hospital conditions of participation, to require reporting of COVID-19 data. We do not recommend the vaccination measures for inclusion in CMS programs. We encourage CMS to partner with hospitals to ensure necessary vaccination data and information are voluntarily reported. Additionally, the measure's exclusions and exceptions differ from the other COVID-19 vaccination measures under consideration (namely, MUC20-0045 Vaccination by Clinicians). Exclusions for MUC20-0045 include the vaccine being unavailable and patient refusal. These exclusions are not listed for MUC20-0044 (Vaccination Coverage among Healthcare Personnel).

Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the inclusion of this measure across the multiple quality programs. We would ask that the CDC ensure that the data capture is identical or as close as possible as what is collected for influenza immunization to minimize reporting burden. For example, the FAH recommends that the data be reported across larger groups of employees using the same 4 category scheme for employee classification as influenza (i.e., staff on payroll, licensed independent practitioners, adult students/trainees/volunteers, other contract personnel). In addition, the CDC must continuously revise and update this measure in coordination with other measure developers with similar measures. These revisions should be based on emerging evidence, newly approved vaccinations, and feedback from the field to ensure that each measure reflects the most current knowledge and evidence and can be easily collected and reported. Because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
The Society for Healthcare Epidemiology of America	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support with Potential for Mitigation. As expressed in a recent policy statement, SHEA believes that all health care personnel (HCP) should be immunized pursuant to CDC and ACIP recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations. However, we support the preliminary recommendation against MUC20-0044's use in any CMS programs – MIPS, IRF QRP, LTCH QRP, SNF QRP, ASCQR, ESRD QIP, Hospital IQR, Hospital OQR, IPR, or PCHQR – at this stage of vaccine deployment. The vaccine's cold-chain storage requirements often limit it to major centers, confounding measurement efforts. Although the measure specifications imply the vaccine should be universally administered, its safety is unproven in certain populations (e.g., pregnant women and immunocompromised patients) and an EUA-authorized vaccine cannot be mandated. Based on our experience, a significant percentage of HCPs are not receiving the vaccine, which could be reflective of vaccine hesitancy or future appointments, among other factors. Furthermore, HIPAA may present a barrier to compiling the data needed to meet the measure. Vaccine administration, while logged in state immunization registries, may not be recorded in EHRs and retrievable by providers responsible for the measure.
Federation of American Hospitals	Yes; support for inclusion in the program.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0044
Other Measure Identification Numbers	N/A
Title	MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel
Program	PPS-Exempt Cancer Hospital Quality Reporting
Workgroup	MAP Hospital
In what state of development is the measure?	Early Development
State of Development Details	Measure is in Early Development.
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among healthcare personnel (HCP) in IPPS hospitals, inpatient rehabilitation facilities (IRFs), long-term care hospitals (LTCHs), inpatient psychiatric facilities, ESRD facilities, ambulatory surgical centers, hospital outpatient departments, skilled nursing facilities, and PPS-exempt cancer hospitals.
Numerator	Cumulative number of HCP eligible to work in the hospital or facility for at least one day during the reporting period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of HCP eligible to work in the healthcare facility for at least one day during the reporting period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	HCP with contraindications to SARS-CoV-2 vaccination.
Measure type	Process
What is the NQF status of the measure?	Never submitted
NQF ID number	0000
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A

Is the measure being submitted exactly as endorsed by NQF?	N/A
If not exactly as endorsed, describe the nature of the differences	N/A
What data sources are used for the measure?	National Healthcare Safety Network
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	None
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	Preventative Care
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	Promote Effective Prevention and Treatment of Chronic Disease
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	Preventative medicine
What is the target population of the measure?	IRF HCP

Is this measure an eCQM?	No
If eCQM, enter Measure Authoring Tool (MAT) number	N/A
If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification?	No
Comments	N/A
Measure steward	Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	Budnitz, Daniel MD, MPH, CAPT USPHS. Director, Medication Safety Program; Division of Healthcare Quality Promotion; Centers for Disease Control and Prevention. 404-498-0634 dbudnitz@cdc.gov
Primary Submitter Contact Information	Adams, Ariel MSN, RN, AGCNS-BC Division of Chronic and Post Acute-Care (DCPAC), Centers for Medicare and Medicaid Services (CMS). 410.786.8571 Ariel.Adams@cms.hhs.gov
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A
Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the	N/A

measure in each year?	
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	New measure never reviewed by MAP Workgroup or used in a CMS program
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	The data needed to calculate this measure will be collected through the COVID-19 Modules on the NHSN website (https://www.cdc.gov/nhsn/covid19/index.html).
How is the measure expected to be reported to the program?	Web Interface
Is this measure similar to and/or competing with measure(s) already in a program?	No
Which existing measure(s) is your measure similar to and/or competing with?	N/A
How will this measure be distinguished from other similar and/or competing measures?	N/A

Rationale for how this measure will add to the CMS program	N/A
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	Analysis of the score distributions of other HCP vaccination measures in post-acute care, including the Influenza Vaccination among Healthcare Personnel (NQF #0431) measure adopted in the IRF QRP, demonstrate variability in the quality measure scores nationally.
Unintended consequences	IRFs may mistakenly administer the vaccine to HCP with contraindications to administration in an attempt to improve their measure score, despite such HCP being excluded from the measure calculation.
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	Health care practice requires close personal exposure to patients, contaminated environment, or infectious material from patients with SARS-CoV-2, putting HCP at high risk of infection and contributing to further spread of COVID-19. (Nguyen et al. 2020) In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and transmission of SARS-CoV-2. Sufficient vaccination coverage of HCP can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in health care facilities, thereby protecting the health of both HCP and patients.

Preliminary Analysis – MUC ID: MUC20-0044 SARS-CoV-2 Vaccination Coverage among Healthcare Personnel

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been reviewed by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. There is a measure in the program set addressing influenza vaccination coverage (NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel), but no measures addressing SARS-CoV-2 vaccination. Vaccination coverage for SARS-CoV-2 is of particular importance to reduce SARS-CoV-2-related morbidity and mortality among HCP and patients within cancer hospitals.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The developer provides information from a prospective, observational cohort study illustrating the increased risk of reporting a positive COVID-19 test for front-line healthcare workers (Nguyen et al., 2020). Both the National Academies of Sciences, Engineering, and Medicine and the Centers for Disease Control identify healthcare workers as the highest-priority for SARS-CoV-2 vaccination. The developer states that sufficient vaccination coverage of healthcare personnel (HCP) can protect the health of the nation's healthcare workforce and reduce transmission of SARS-CoV-2 in healthcare facilities, thereby protecting the health of both HCP and patients. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in the PCHQR program. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronovirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (November 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap. Existing healthcare personnel vaccinations measures demonstrate variation in performance across facilities.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Unclear	This measure provides important information not currently available for this setting or level of analysis. MUC20-0044 is intended for several federal programs, including post-acute care. The developer indicates that this measure will be submitted using the COVID-19 Modules on the NHSN website. However, recent Federal COVID-19 Guidance for Hospital Reporting states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance. The NHSN is the same submission method used for the existing influenza vaccination measure (NQF #0431 Influenza Vaccination Coverage Among Healthcare Personnel). The two measures have different categories for data collection, with the influenza measure collected for three populations: employees, independent licensed practitioners, and adult/student trainees and volunteers. The SARS-CoV-2 measure will be collected for seven job categories: environmental services; nurses; medical assistants and certified nursing assistants; respiratory therapists; pharmacists and pharmacy technicians; physicians and other licensed independent practitioners; and other health care practitioners (HCP; such as students or volunteers) not included in the previously listed categories. It is unclear what impact the difference in data reporting and in data collection categories may have on efficiency or alignment. Alignment considerations will be more important should vaccination against COVID-19 remain a long-term concern. The durability of immunological response is not currently well understood but may weaken quickly, suggesting that COVID-19 vaccination rates may be a long-term measurement issue.
Can the measure be feasibly reported?	Unclear	Facilities currently participating in PCHQR already report other measures, including those capturing healthcare personnel vaccination with other vaccines, using NSHN. It is not clear what additional burden this measure would represent or if a different reporting mechanism will be used for the SARS-CoV-2 measure based on recent Federal COVID-19 Guidance for Hospital Reporting that states that as of July 15, 2020, hospitals should no longer report COVID-19 information to the NHSN site, but to use a different method provided in the guidance.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use. The measure developer theorizes that facilities could mistakenly vaccinate individuals with contraindications in an attempt to maximize their score. Individuals with contraindications are excluded from the measure.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	
Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply by that time. • Appropriate for the rural community and vaccination coverage of healthcare workers is important. Data collection issues: • None Calculation issues: • None Unintended consequences: • None Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.1 1 – 0 vote 2 – 0 vote 3 – 2 votes 4 – 12 votes 5 – 3 votes

Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections in healthcare personnel and the patients for whom they provide care.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage among healthcare personnel and providing feedback to cancer hospitals will allow facilities to benchmark coverage rates and improve coverage in their facility. Reducing rates of COVID-19 in healthcare personnel may reduce transmission among patients and reduce instances of staff shortages due to illness. Prior to use in PCHQR Program, this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Do not support
Pfizer	We concur that this vaccination measure would add value, given the current shortages in the healthcare workforce, in ensuring that the personnel are available to provide patient care. In the numerator, the definition of healthcare personnel is broadly defined. In contrast, ACIP defines healthcare personnel to include all paid and unpaid persons as serving in settings who have the potential for direct or indirect exposure to patients or infectious materials. NQF should consider this definition.
American Medical Association	The AMA seeks clarification on whether this measure is for MIPS or IQR. The MUC list listed the measure under IQR. We encourage the CDC to revise and/or update the measure as new evidence comes forward and based on feedback received from the field.
Premier	Premier believes that adoption of this measure is premature. At this time, it unclear if this is a one-time measure for the duration of the ongoing public health emergency or if it will become an annual vaccination. CMS has the authority to request this information outside of quality programs. For example, rates of vaccination could be captured through other COVID-19 reporting mechanisms. Additional clarity is also needed on how health care professionals are defined for purposes of this measure.
America's Essential Hospitals	Members of America's Essential Hospitals understand the value of data and have reported COVID-19 data throughout the pandemic. America's hospitals responded diligently to gather, report, and update data related to COVID-19 and will continue to do so.

	However, the collection of vaccination data should not be tied to accountability programs, such as the Inpatient Quality Reporting Program. In doing so, CMS indicates these measures could be considered in additional programs, including the overall hospital star ratings or the Value-Based Purchasing Program. There are more appropriate levers for achieving the intended goal of "sufficient vaccination coverage" of health care personnel. In fact, the administration has used other levers, including hospital conditions of participation, to require reporting of COVID-19 data. We do not recommend the vaccination measures for inclusion in CMS programs. We encourage CMS to partner with hospitals to ensure necessary vaccination data and information are voluntarily reported. Additionally, the measure's exclusions and exceptions differ from the other COVID-19 vaccination measures under consideration (namely, MUC20-0045 Vaccination by Clinicians). Exclusions for MUC20-0045 include the vaccine being unavailable and patient refusal. These exclusions are not listed for MUC20-0044 (Vaccination Coverage among Healthcare Personnel).
Federation of American Hospitals (FAH)	The Federation of American Hospitals (FAH) supports the inclusion of this measure across the multiple quality programs. We would ask that the CDC ensure that the data capture is identical or as close as possible as what is collected for influenza immunization to minimize reporting burden. For example, the FAH recommends that the data be reported across larger groups of employees using the same 4 category scheme for employee classification as influenza (i.e., staff on payroll, licensed independent practitioners, adult students/trainees/volunteers, other contract personnel). In addition, the CDC must continuously revise and update this measure in coordination with other measure developers with similar measures. These revisions should be based on emerging evidence, newly approved vaccinations, and feedback from the field to ensure that each measure reflects the most current knowledge and evidence and can be easily collected and reported. Because we anticipate that this measure will undergo substantial changes within and across reporting years, the FAH does not believe that it should be used for payment decisions nor should it be publicly reported until the underlying evidence is stable and reporting of the measure has occurred for several years.

Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
Alliance of Dedicated Cancer Centers	We support the recommendation to Committee's recommendation not to support the measure for inclusion at this time, with the opportunity for mitigation. While Covid is certainly a national healthcare priority, and we support evidence-based measures for the protection of healthcare workers and patients such as the current healthcare provider influenza vaccination measure, we have several concerns with the measure as currently written: • Due to the evolving nature of Covid-19 and the fact that the vaccines are new, long-term efficacy is undefined. As the MAP noted, the evidence is still emerging. • Making vaccination a requirement of employment is controversial as the long-term side effects are as of yet unknown • The measure specifications need to be refined and tested prior to implementation in a quality

	reporting program, and certainly before use in public display • Implementing this measure without long term knowledge of the annual recurrence rate of this virus is problematic. Furthermore, the long-term immunity conveyed by the vaccine and need for an annual measure versus a one-time phenomenon is not yet known. We are supportive of the concept of healthcare worker vaccinations that are evidence-based and in encouraging accountability via their including in quality reporting programs, but believe this vaccine and measure are not mature enough to warrant inclusion as currently written. Thank you for the opportunity to comment.
The Society for Healthcare Epidemiology of America	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support with Potential for Mitigation. As expressed in a recent policy statement, SHEA believes that all health care personnel (HCP) should be immunized pursuant to CDC and ACIP recommendations and that only medical contraindications should be accepted as a reason for not receiving such vaccinations. However, we support the preliminary recommendation against MUC20-0044's use in any CMS programs – MIPS, IRF QRP, LTCH QRP, SNF QRP, ASCQR, ESRD QIP, Hospital IQR, Hospital OQR, IPR, or PCHQR – at this stage of vaccine deployment. The vaccine's cold-chain storage requirements often limit it to major centers, confounding measurement efforts. Although the measure specifications imply the vaccine should be universally administered, its safety is unproven in certain populations (e.g., pregnant women and immunocompromised patients) and an EUA-authorized vaccine cannot be mandated. Based on our experience, a significant percentage of HCPs are not receiving the vaccine, which could be reflective of vaccine hesitancy or future appointments, among other factors. Furthermore, HIPAA may present a barrier to compiling the data needed to meet the measure. Vaccine administration, while logged in state immunization registries, may not be recorded in EHRs and retrievable by providers responsible for the measure.

Measure Information

Characteristic	Submitted Information
MUCID	MUC20-0048
Other Measure Identification Numbers	NHSN COVID VAX 4: SARSCoV-2 Vaccination Coverage for Persons with Renal Disease Receiving Dialysis
Title	SARS-CoV-2 Vaccination Coverage for Patients in End-Stage Renal Disease (ESRD) Facilities
Program	End-Stage Renal Disease QIP
Workgroup	MAP Hospital
In what state of development is the measure?	N/A
State of Development Details	N/A
Measure Description	This measure tracks SARS-CoV-2 vaccination coverage among patients of dialysis facilities including those with end-stage renal disease (ESRD) and receiving maintenance dialysis and those with acute kidney injury (AKI) including in-center hemodialysis, home hemodialysis, or peritoneal dialysis.
Numerator	Cumulative number of patients who were eligible for vaccination during the reporting time-period and who received a complete vaccination course against SARS-CoV-2 since the date vaccine was first available or on a repeated interval if revaccination on a regular basis is needed. A completed vaccination course may require 1 or more doses depending on the specific vaccine used. Vaccination coverage is defined as a measure of the estimated percentage of people in a sample or population who received a specific vaccine or vaccines.
Denominator	Number of patients under care for first 2 working days of reporting month in the ESRD facility eligible for vaccination during the reporting time-period, excluding persons with contraindications to SARS-CoV-2 vaccination.
Exclusions	Patients with contraindications to SARS-CoV-2 vaccination and patients who refuse vaccination
Measure type	N/A
What is the NQF status of the measure?	N/A
NQF ID number	N/A
Year of next anticipated NQF CDP endorsement review	N/A
Year of most recent NQF Consensus Development Process (CDP) endorsement	N/A
Is the measure being submitted exactly as endorsed by NQF?	N/A
If not exactly as endorsed,	N/A

describe the nature of the differences	
What data sources are used for the measure?	Sources for required data elements include facility administrative data and patient vaccination records.
If EHR or Administrative Claims or Chart-Abstracted Data, description of parts related to these sources.	N/A
At what level of analysis was the measure tested?	N/A
In which setting was this measure tested?	N/A
What NQS priority applies to this measure?	N/A
What one primary meaningful measure area applies to this measure?	N/A
What secondary meaningful measure area applies to this measure?	N/A
What one primary healthcare priority applies to this measure?	N/A
What secondary healthcare priority applies to this measure?	N/A
What area of specialty best fits the measure?	May be used for performance improvement or for reporting programs. Not appropriate for payment programs.
What is the target population of the measure?	N/A
Is this measure an eCQM?	N/A
If eCQM, enter Measure Authoring Tool (MAT) number	N/A
If eCQM, does the measure	N/A

have a Health Quality Measures Format (HQMF) specification?	
Comments	**Data Accuracy:** Variation may exist with self-reporting of vaccination status to the facilities if received the vaccines outside the facilities. **Measure Analysis Suggestions:** The number of patients who have completed a partial course of COVID-19 vaccination may be calculated as an additional measure of progress toward completed vaccination. • Partial Vaccination Denominator: Number of patients of the ESRD facility eligible for vaccination during the reporting time-period, excluding those persons with contraindications to SARS-CoV-2 vaccination • Partial Vaccination Numerator: Number of patients eligible for vaccination during the reporting time-period and who received at least one dose of a vaccination course that requires 2 or more doses for completion. The number of patients with documented contraindications to vaccination and who decline vaccination may be used as additional denominator exclusions for alternate analyses. In addition, analyses may be stratified by vaccine manufacturer and type of dialysis (in-center, home and peritoneal).
Measure steward	The Centers for Disease Control and Prevention
Long-Term Measure Steward (if different)	N/A
Measure Steward Contact Information	N/A
Primary Submitter Contact Information	N/A
Long-Term Measure Steward Contact Information	N/A
Secondary Submitter Contact Information	N/A
Was this measure proposed for a previous year's MUC list?	No
In what prior year(s) was this measure proposed?	N/A
What were the programs that NQF MAP reviewed the measure for in each year?	N/A

Why was the measure not recommended in those year(s)?	N/A
What were the MUC IDs for the measure in each year?	N/A
NQF MAP report page number being referenced for each year	N/A
What was the NQF MAP recommendation in each year?	N/A
List the NQF MAP workgroup(s) in each year	N/A
What is the history or background for including this measure on the new MUC list?	N/A
Range of years(s) this measure has been used by CMS Program(s)	N/A
What other federal programs are currently using this measure?	N/A
Evidence that the measure can be operationalized	N/A
How is the measure expected to be reported to the program?	Percentage of patients who have received a completed a vaccination course against SARS-CoV-2. This metric is intended to be calculated on a monthly basis, but could be collected on another interval.
Is this measure similar to and/or competing with measure(s) already in a program?	N/A
Which existing measure(s) is your measure similar to and/or competing with?	N/A

How will this measure be distinguished from other similar and/or competing measures?	N/A
Rationale for how this measure will add to the CMS program	The virus causing Coronavirus Disease 2019 (COVID-19) can cause outbreaks in persons with chronic disease who may also be at high risk for severe disease. Preventing COVID-19 among persons with ESRD is crucial to avoiding severe illness and deaths for these persons. In-center dialysis patients are exposed to the healthcare environment at minimum three times a week for 4 hours. In addition to infection control and early detection of COVID-19, vaccination is expected to be one of the most effective ways to prevent COVID-19 and its transmission.
If this measure is being proposed to meet a statutory requirement, please list the corresponding statute.	N/A
Evidence of performance gap	N/A
Unintended consequences	N/A
Which clinical guideline(s)?	N/A
Briefly describe the peer reviewed evidence justifying this measure	N/A

Preliminary Analysis – MUC ID: MUC20-0048 SARS-CoV-2 Vaccination Coverage for Patients in End-Stage Renal Disease (ESRD) facilities

Criteria	Yes/No	Justification and Notes
Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?	Yes	This is a new measure that has not been review by a MAP Workgroup or used in a CMS program. SARS-CoV-2 vaccination is a national healthcare priority. There are no measures addressing vaccination coverage currently in the ESRD QIP set. Vaccination coverage for SARS-CoV-2 is of particular importance to the vulnerable patient population served by outpatient dialysis facilities.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?	No	This is a process measure. Vaccines to prevent SARS-CoV-2 infection are considered the most promising approach to addressing the current pandemic (Jeyanathan et al., 2020). The Center for Disease Control and Prevention (CDC) notes that 8 out of 10 COVID-19 deaths reported in the US have been in adults 65 years old and older. The measure developer notes that preventing COVID-19 among persons with ESRD is crucial to avoiding severe illness and deaths, as in-center dialysis patients are exposed to the healthcare environment several times a week. Before any vaccine receives FDA approval for emergency use, the vaccine must first be shown to be safe and effective through clinical trials (CDC, 2020). Early reports for vaccines in development suggest that they may be more than 90% effective in the prevention of transmission of the SARS-CoV-2 (Mahase, 2020). While early evidence submitted to the FDA for emergency use authorization is promising, the full range of evidence is still emerging.
Does the measure address a quality challenge?	Yes	This measure covers a topic not currently addressed in ESRD QIP. It will be among a set of the first quality measures to address prevention of COVID-19. In late November 2020, the Johns Hopkins Coronavirus Resource Center reported almost 12.6 million COVID-19 cases with almost 260,000 deaths in the United States. Both numbers were increasing rapidly. At the time of drafting this preliminary analysis (early December 2020), no SARS-CoV-2 vaccines have been approved by the Federal Drug Administration (FDA). Performance on the measure is therefore essentially zero, maximizing the performance gap.
Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?	Yes	This measure provides important information not currently available for this setting or level of analysis.
Can the measure be feasibly reported?	Unclear	Sources of required data elements for this measure include facility administrative data and patient vaccination records. The proposed measure has not been specified as to whether the required data elements are available in electronic format. The measure developer notes that variation may exist with self-reporting of vaccination status to the facilities if the vaccines are received outside the facility.
Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?	Unclear	Specifications are incomplete pending approved vaccines and vaccination protocols, but what is available is applicable and appropriately specified.

If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure have been identified?	N/A	This is a new measure that is not currently in use.
PAC/LTC Core Concept?	N/A	
Impact Act Domain	N/A	
Hospice High Priority Areas	N/A	
Rural Workgroup Input	[redacted]	Relative priority/utility: • Vaccine access and distribution may be an issue, but since this measure won't be implemented until 2022, there may be better distribution and supply. • Appropriate for the rural community. • ESRD patients are a high-priority group. Data collection issues: • None Calculation issues: • None Unintended consequences: • None identified Votes: *Range is 1 – 5, where higher is more relevant to rural.* Average: 4.2 1 – 0 vote 2 – 0 vote 3 – 1 vote 4 – 11 votes 5 – 4 votes

Preliminary Analysis Recommendation	Do not support with potential for mitigation	The mitigation points for this measure prior to implementation are that the evidence should be well documented, and that the measure specifications should be finalized, followed by testing and NQF endorsement. The proposed measure represents a promising effort to advance measurement for an evolving national pandemic. The incomplete specifications require immediate mitigation and further development should continue.
Summary: What is the potential value to the program measure set?	[redacted]	This measure would add value to the program measure set by providing visibility into an important intervention to limit COVID-19 infections.
Summary: What is the potential impact of this measure on quality of care for patients?	[redacted]	Collecting information on SARS-CoV-2 vaccination coverage and providing feedback to outpatient dialysis facilities will facilitate benchmarking and quality improvement. Vaccination coverage will reduce transmission and associated morbidity and mortality. Prior to use in the ESRD QIP Program, this important measure should have the supporting evidence well-documented, and be fully developed, followed by testing and receipt of NQF endorsement.

Measure Comments

Author	Submitted Comment
University of Colorado Medicine	Yes, under certain circumstances
Kidney Care Partners (KCP)	Thank you for the opportunity to comment on the Measures Under Consideration (MUCs) for Federal Health Programs prior to the Measure Applications Partnership (MAP) Workgroup and Coordinating Committee meetings. Kidney Care Partners (KCP) is a coalition of members of the kidney care community that includes the full spectrum of stakeholders related to dialysis care—patient advocates, healthcare professionals, dialysis providers, researchers, and manufacturers and suppliers—organized to advance policies that improve the quality of care for individuals with chronic kidney disease and end stage renal disease (ESRD). We greatly appreciate the MAP undertaking this important work, and we offer the following comments addressing measures proposed for use in the ESRD Quality Incentive Program (QIP). MUC 20-0048—SARS-CoV-2 Vaccination Coverage for Patients in ESRD Facilities (CDC) SARS-CoV-2 vaccination of patients and healthcare personnel in ESRD facilities is paramount; however, we again note the information provided in the MUC list lacks the specificity required to meaningfully evaluate this new measure at this time. Detailed specifications and information on measure performance (reliability and validity) are both needed during the MAP process to allow stakeholders to determine if the metrics are feasible and will provide an accurate, actionable assessment of this most critical clinical process. And as always, we strongly recommend the measure be submitted to NQF for endorsement, a general pre-requisite for KCP to support inclusion of a measure in any accountability program. KCP again thanks you for the opportunity to provide early comments on this important work

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Measure Comments (Post-Workgroup Meeting)

Author	Submitted Comment
The Society for Healthcare Epidemiology of America	The Society for Healthcare Epidemiology of America (SHEA) generally agrees with the Measure Application Partnership's (MAP) preliminary recommendation of Do Not Support With Potential for Mitigation. SHEA further recommends that the MUC remove MUC20-0048 from the list of measures under consideration because it would be premature to consider the measure for the ESRD QIP at this time. While patients with ESRD are a critical population, they do not currently fall within the first several prioritization groups identified by the CDC. It is also imperative that, prior to the introduction of a population-specific quality measure, further evidence support the effectiveness of the vaccine among such patients. We recommend removing the measure from consideration for the 2020-2021 MUC cycle, with the potential to revisit it next year.
Kidney Care Partners	MUC 20-0048—SARS-CoV-2 Vaccination Coverage for Patients in ESRD Facilities (CDC) KCP agrees that SARS-CoV-2 vaccination in ESRD facilities is paramount. However, while every KCP Member Organization is committed to and has prioritized COVID vaccination for both patients and healthcare personnel, we do not believe a performance metric will effectively drive this clinical process at this early juncture; we thus do not support MUC 20-0048 for use in the ESRD QIP. We agree with the Hospital Workgroup that the information provided to the MAP lacks the specificity required to meaningfully evaluate the proposed measure, but more, we believe the

	introduction of the measure is extremely premature. We note the very specific details needed to build a meaningful, valid, and reliable performance measure (e.g., appropriate exclusions, contraindications, dosing schedules, and vaccination intervals) will not be fully fleshed out in the foreseeable future. We fear a rush to develop this fledgling concept while our understanding of SARS-CoV-2 is still rapidly evolving will result in an unsound performance measure that will unnecessarily and unintentionally complicate this most critical clinical process during this unprecedented public health emergency. As a matter of process, we also reiterate our longstanding position that it is critical that detailed specifications and information on measure performance (reliability and validity) be provided during the MAP process to allow stakeholders to determine if metrics are feasible and will provide an accurate, actionable assessment of care. It is also critical to note that the SARS-CoV-2 vaccines are authorized for use under an FDA Emergency Use Authorization (EUA). As EUA documents are viewed as recommendations and do not establish legally enforceable processes of care, any performance measure assessing COVID vaccination would be wholly inappropriate for use in the ERSD QIP, a value-based purchasing program which requires providers to report and meet or exceed performance standards to avoid payment penalties. KCP thus believes that even when fully specified and tested, MUC 20-0048 cannot ethically be used in the QIP until the COVID-19 public health emergency ends and/or the vaccines have received full approval from the FDA. When the above conditions have been met, we support the Hospital Workgroup's recommendation that the measure be submitted to NQF for endorsement, a general pre-requisite for KCP to support inclusion of a measure in any accountability program.
American Hospital Association	The AHA appreciates CMS's rationale behind introducing this unspecified measure and understands the urgency of addressing COVID-19 vaccination rates among highly vulnerable ESRD patients. However, we urge extreme caution in implementing this measure in the future as its use could have negative unintended consequences and might not be a useful tool in encouraging vaccination. We agree with the MAP Workgroup's recommendation of Do Not Support with Potential For Mitigation, mitigating factors including well documented evidence of provider influence on vaccination rates and finalized specifications coupled with testing and endorsement. Detailed and thoroughly tested measure specifications will be especially important given that the measure is based upon self-reported data, making it critical that measure variation does not stem from inconsistency in how providers collect data and report their performance. While this measure is focused on an appropriate population, performance on the measure might not be indicative of provider behavior as the current vaccine distribution strategy has not targeted ESRD facilities. We encourage CMS to consider other ways of addressing this issue as it continues to develop this measure. For example, this might be an opportunity to use non-traditional sources of information, like mobile application tracking, to enhance self-reported data. In addition, this measure might better reflect performance if it were specified as a structural measure that determined whether the facility offered on-site vaccinations or whether patients were offered a vaccine. Similar to our comments on the healthcare personnel vaccination measure, we have concerns regarding the lack of alignment between this measure and that under consideration for the MIPS program. The numerator and exclusions for the two measures differ, and while some of those discrepancies are logical considering the differences in patient populations, we encourage CMS to seek alignment across the continuum of care as much as possible so that clinicians are working towards the same goals.

Federation of American Hospitals	Yes; support for inclusion in the program.