NATIONAL QUALITY FORUM
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Measure Applications Partnership (MAP) Hospital Workgroup: 2021-2022 Cycle Preliminary Analyses

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End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

MUC2021-101 Standardized Readmission Ratio (SRR) for dialysis facilities

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
End-Stage Renal Disease (ESRD) Quality Incentive Program (QIP)

Workgroup
Hospital

Measure Description
The Standardized Readmission Ratio (SRR) for a dialysis facility is the ratio of the number of observed index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm. Note that the measure is based on Medicare-covered dialysis patients.

Numerator
Each facility's observed number of hospital discharges that are followed by an unplanned hospital readmission within 4-30 days of discharge.

Numerator Exceptions
N/A

Denominator
The denominator for a given facility is the expected number of the observed index hospital discharges that result in an unplanned readmission in days 4-30 and that are not preceded by an unplanned or competing event. The expectation accounts for patient-level characteristics, including measures of patient comorbidities, and the discharging hospital, and is based on estimated readmission rates for an overall population norm that corresponds to an "average" facility.

Denominator Exclusions
A live inpatient hospital discharge is excluded if any of the following hold:

- Associated with a stay of 365 days or longer
- It is against medical advice
- It Includes a primary diagnosis of cancer, mental health or rehabilitation
- It Includes revenue center codes indicating rehabilitation
- It occurs after a patient's 12th hospital discharge in the calendar year

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- It is from a PPS-exempt cancer hospital
- It is followed within 3 days by any hospitalization (at acute care, long-term care, rehabilitation, or psychiatric hospital or unit) or any other competing event

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
N/A

What is the target population of the measure?
Dialysis Patient - Medicare

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Nephrology

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Claims Data; Registries

If applicable, specify the data source
N/A

If EHR 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 one healthcare domain applies to this measure?
Seamless Care Coordination

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

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CMIT ID
1689

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Failed Endorsement

NQF ID Number
NQF # 2496

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change.

Range of years this measure has been used by CMS Programs
ESRD QIP 2016 - Present

What other federal programs are currently using this measure?
End-Stage Renal Disease (ESRD) Quality Incentive Program; Dialysis Facility Compare

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Several studies and commentaries strongly suggest pre- and post-discharge interventions within the purview of dialysis providers may reduce the risk of unplanned readmissions within the ESRD chronic dialysis population (Assimon, Wang, and Flythe 2018; Plantinga et al 2018; Flythe et al 2017, 2016; Chan et al 2017; Assimon and Flythe 2017; Plantinga and Jaar 2017). Plantinga et al (2018) found that interventions in the immediate post-discharge period were associated with reduced readmission risk among hemodialysis patients. They also suggest that post-discharge processes of care may help identify certain patients at higher risk for readmission, creating opportunities for dialysis providers to initiate interventions to reduce readmissions. A number of 'patient-at-discharge' characteristics were found by Flythe et al (2017) to be associated with greater readmission risk. These included 10 or more outpatient medications at time of admission; catheter vascular access; three or more hospital admissions in the prior year; and intradialytic hypotension. The authors suggest that modifiable processes of care such as

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care transitions and targeted medication education may reduce the risk of readmissions among dialysis patients recently discharged. Chan and colleagues (2009) found that certain post-discharge assessments and changes in treatment at the dialysis facility may be associated with a reduced risk of readmission. Assessments included hemoglobin testing and modification of EPO dose; mineral and bone disease testing and modification of vitamin D; and, importantly, modification of dry weight after discharge. The risk of unplanned hospital readmission was reduced when these assessments were completed within the first seven days post-hospital discharge. In a commentary (Wish 2014) the Chan 2009 study and several others are cited as examples of the potential for care coordination to reduce readmissions among ESRD dialysis patients. The findings from Chan 2009 are further supported by results from a recent study (Lin et. al. CJASN, 2019) comparing principal diagnosis of index hospitalizations and their associated readmissions. Tables included in the paper's supplementary materials clearly demonstrate that a significant portion of readmission principal discharge diagnoses are for dialysis-related conditions. For example, regardless of the index hospitalization cause (i.e. infectious, endocrine, cardiovascular, GI, dermatologic, renal, etc), the top principal discharge diagnosis lists for related readmissions prominently included diagnoses typically associated with fluid overload and failure of fluid management in dialysis patients (fluid overload, hypertension, CHF, etc). These results support the early findings from Chan 2009, nearly a decade earlier, showing that adjustment of patient target weight in the early post-hospitalization discharge period (to adjust for the frequent weight loss and/or in-hospital re-assignment of a lower post-dialysis target weight) is a likely mechanism for a substantial minority of unplanned readmissions in the US chronic dialysis population.

Facility structures of care may also impact risk of readmission. One study reported that lower nurses-to-total staff and higher patient-to-nurse ratios were associated with significantly worse 30-day readmission performance (Chen et al 2019).

Finally, findings from the first two performance years of the Center for Medicare and Medicaid Innovation's Comprehensive ESRD Care Initiative suggest care coordination may reduce readmission risk (Marrufo et al, 2019). The findings of this controlled study showed an overall decrease in the percentage of Medicare beneficiaries with at least one readmission, among those aligned to an ESRD Seamless Care Organization, relative to a matched comparison group of facilities.

Studies in the non-dialysis setting have cited post-interventions or a combination of pre-and post-discharge interventions as drivers for reducing unplanned readmissions (Dunn 1994; Bostrom 1996; Dudas 2001; Azevedo 2002; Coleman 2004; Coleman 2006; Balaban 2008; Braun 2009; Naylor 1994; McDonald 2001; Creason 2001; Ahmed 2004; Anderson 2005; Jack 2009; Koehler 2009; Parry 2009). However, a recent study and related commentary challenge the reported magnitude of reductions in hospital-wide readmissions since 2010, as part of the publicly reported Hospital Wide Readmission (HWR) measure for the Hospital Readmission Reduction Program (HRRP) (Wadhera, Yeh, and Joynt-Maddox 2019; Ody et al 2019). They suggest the potential driver of these reductions is in part attributed to a change in diagnosis coding policy for inpatient claims that took effect in October 2012. While it is not yet settled whether the reductions were primarily or only nominally driven by the ability of hospitals to report more condition diagnoses, resulting in more robust comorbidity risk adjustment in the measure, the concern has generated attention about whether reported improvements in readmission rates is a result of the HWR and by extension better care delivery by hospitals. These concerns are not considered germane to drivers of readmission reduction based on the dialysis facility readmission measure. The SRR was implemented by CMS in 2015, after the 2012 coding changes took effect.

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Therefore trends in dialysis patient 30-day readmissions only reflect the period since the claims based diagnoses coding changes, and observed reductions since that time are not considered an artifact of the 2012 inpatient diagnosis coding changes.

Collectively this body of evidence provides support on interventions that may reduce the risk of unplanned readmissions among ESRD dialysis patients. Effective interventions include enhanced care coordination and interventions performed prior to and immediately following the post-discharge period.

Evidence that the measure can be operationalized

N/A

How is the measure expected to be reported to the program?

Clinical Quality Measure (CQM) Registry; Claims

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

To address the problem of simultaneously monitoring a large number of facilities and to take account of the intrinsic unexplained variation among facilities, we used the approach described in Kalbfleisch and Wolfe (2013). This method is based on the empirical null as described in Efron (2004, 2007). The p-value for each facility is converted to a Z-score, stratified into four groups based on patient-years within each facility. The empirical null corresponds to a normal curve that is fitted to the center of each Z-score histograms using a robust M-estimation method. The standard deviation of empirical null distribution is then used for a reference distribution (with mean 0) to identify outlier facilities. This method aims to separate underlying intrinsic variation in facility outcomes from variation that might be attributed to poor (or excellent) care.

The flagging rates presented in Table 4 are based on flagging those facilities in the upper tail (area=5%) of the empirical null distribution in each stratum. (The empirical null p-value is 5% or less.)

Table 4. Facilities Identified as Performing Worse than Expected for 4-30 Day Readmission Rate, 2018

Facility Size (Patient-years)	No. of Facilities[1]	SRR: Worse than Expected
1st Quartile	1,733	101 (5.83%)
2nd Quartile	1,733	80 (4.62%)
3rd Quartile	1,734	79 (4.56%)
4th Quartile	1,733	145 (8.37%)
Total	6,933	405 (5.84%)

[1] Four facilities did not receive a facility size.

Unintended Consequences

None anticipated

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Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
6500 dialysis facilities

Estimate of Annual Improvement in Measure Score
Not Applicable

Type of Evidence to Support the Measure
Other: environmental scan performed to support measure development

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
N/A

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

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Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
No

If yes, choose all methods that obtained clinician and/or provider input
N/A

Total Number of Clinicians/Providers Consulted
N/A

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
N/A

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

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How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
The value obtained for the inter-unit reliability (IUR) is low to moderate in size. The profile inter-unit reliability (PIUR) is larger and demonstrates that the SRR is effective at detecting outlier facilities and statistically meaningful differences in performance scores across dialysis facilities.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Other: IUR

Reliability Testing Sample Size
6937

Reliability Testing Statistical Result
Overall, we found that IUR = 0.35 The PIUR is 0.61. The PIUR measures reliability in terms of reflagging rates but is placed on the same scale as IUR. The higher PIUR compared to the IUR indicates the presence of outliers or heavier tails among the providers, which is not captured in the IUR itself. If there are no outliers, one should expect the PIUR to be similar to the IUR; but in cases where there are outlier providers, even measures with a low IUR can have relatively high PIUR and can be very useful for identifying extreme providers.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Correlation

Validity Testing Sample Size
6937 Medicare-certified dialysis facilities

Validity Testing Statistical Result
The measure is positively correlated with the one-year Standardized Hospitalization Ratio for Admissions ($r = 0.39$, $p < 0.0001$), the Standardized Mortality Ratio ($r = 0.10$, $p < 0.0001$), and long term catheter use ($r = 0.04$, $p = 0.0006$). The SRR is negatively correlated with the rate of patients using a fistula ($r = -0.06$, $p < 0.0001$).

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Validity Testing Interpretation of Results

The SRR is a measure of hospital use, comprising many causes of hospitalization. The TEP considered devising cause-specific SRRs but recommended the use of overall SRR measures due to various reasons, including the lack of clear consensus on which causes are modifiable by the dialysis facility and concerns about gaming the system if certain conditions are identified.

The validity of the SRR measure is also supported by its association with other known quality measures, which include both dialysis facility outcomes and practices. Higher values of SRR are associated with higher rates of hospitalization and mortality. The SRR is also correlated with other quality measures (listed above), although the correlations are small. The interpretation of the face validity garnered from the 2012 TEP described in the previous submission (above) carries forward to this submission.

Measure performance – Type of Score

Ratio

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

Unadjusted (raw) Readmission Rates:

2016: 0.265

2017: 0.264

2018: 0.263

2016: 6,442 facilities, SRR mean: 0.99, SD: 0.28, min: 0.00, max: 2.61, IQR: 0.33, deciles (10-90): 0.65, 0.78, 0.87, 0.93, 1.00, 1.06, 1.13, 1.20, 1.32

2017: 6,682 facilities, SRR mean: 1.00, SD: 0.28, min: 0.00, max: 2.47, IQR: 0.33, deciles (10-90): 0.66, 0.79, 0.84, 0.94, 1.00, 1.06, 1.13, 1.21, 1.32

2018: 6,937 facilities, SRR mean: 1.00, SD: 0.29, min: 0.00, max: 3.69, IQR: 0.34, deciles (10-90): 0.66, 0.78, 0.87, 0.94, 1.00, 1.06, 1.13, 1.21, 1.34

Benchmark, if applicable

N/A

Measure Contact Information

Measure Steward

Center for Medicare & Medicaid Services

Measure Steward Contact Information

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Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-101 Standardized Readmission Ratio (SRR) for dialysis facilities

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure addresses the high-priority area of Care Coordination for the ESRD QIP. ESRD patients represent a high-risk population with complicated ongoing medical care needs that require high levels of care coordination to prevent adverse events (Chen et al., 2019; Estes et al., 2020). This measure is an updated version of the existing measure, NQF #2496 in ESRD QIP.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is an outcome measure that assesses unplanned readmissions to dialysis facilities. Readmissions can indicate gaps in care coordination or transitions of care (Perl et al., 2017), and the developer provides peer-reviewed evidence that demonstrates that dialysis facilities can implement interventions to reduce the risk of unplanned readmissions.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: More than one-third of hospital discharges for dialysis patients may result in a 30-day readmission (Hickson et al., 2018). This measure calculates a ratio of the number of observed

index discharges from acute care hospitals to that facility that resulted in an unplanned readmission to an acute care hospital within 4-30 days of discharge to the expected number of readmissions given the discharging hospitals and the characteristics of the patients and based on a national norm. The developer presents evidence of a care gap in which 5.84% of sampled facilities performed worse than expected on Standardized Readmission Ratio (SRR) for dialysis facilities, representing an opportunity for improvement.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: This measure is an updated version of the existing measure, NQF #2496, in the ESRD QIP. The ESRD QIP does not contain any other readmission measures. NQF#1789, Hospital-Wide 30-Day, All-Cause, Risk-Standardized Readmission Rate Following Hospitalization, is currently active in the Hospital Inpatient Quality Reporting (IQR) Program.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This is a claims and registry-based measure, and the developer notes that all data elements are in defined fields in a combination of electronic sources. An older version of the measure is already in 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/No: No

Justification and Notes: This measure is fully developed and specified at the dialysis facility level. The All-Cause Admissions and Readmissions Consensus Development Process (CDP) Committee passed the measure on reliability after raising initial concerns regarding the differences in IUR and PIUR (0.35 and 0.61, respectively.) However, the NQF CDP Committee did not pass the measure on validity in agreement with the Scientific Methods Panel (SMP) review, citing concerns about the adequacy of measure correlations presented for validity testing.

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?

Yes/No: No

Justification and Notes: An older version of the measure is currently in use in the ESRD QIP. The developer does not anticipate any unintended consequences.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

Impact Act Domain

Yes/No: N/A

Justification: N/A

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Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- Concern that the measure did not pass NQF endorsement due to validity, but does have importance to patients
- Any measure that require travel puts rural patients at a disadvantage; which can be the case with traveling to dialysis facilities.

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.

Average: 3.3

1 – 0 votes

2 – 5 votes

3 – 1 votes

4 – 8 votes

5 – 1 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- Concern that this measure did not pass NQF endorsement due to validity.
- Gap in equity in kidney care and outcomes

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity

Average: 3.4

1 – 0 votes

2 – 2 votes

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3 – 9 votes
4 – 10 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Do Not Support for Rulemaking

Summary: What is the potential value to the program measure set?
This fully developed and specified measure is an updated version of NQF #2496, which is currently included in the ESRD QIP. The measure addresses the high-priority area of care coordination for the ESRD QIP. The program does not contain any other readmission measures. However, this measure was submitted for NQF Endorsement in Spring 2020 but did not pass scientific acceptability on validity and was not endorsed.

Summary: What is the potential impact of this measure on quality of care for patients?
This measure identifies unplanned readmissions for dialysis patients that may signal remediable gaps in care coordination or transitions of care. Do Not Support for Rulemaking is recommended, due to failure to pass scientific acceptability in NQF Endorsement.

Section 3: Public Comments

Kidney Care Partners (KCP)
Kidney Care Partners (KCP) appreciates the opportunity to comment on the Measures Under Consideration (MUCs) for use in Federal Health Programs for the Measure Applications Partnership (MAP) 2022 Pre-Rulemaking Cycle. 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 single measure proposed by the Centers for Medicare and Medicaid Services (CMS) for use in the ESRD Quality Incentive Program (QIP)—the Standardized Readmission Ratio for Dialysis Facilities (SRR, previously NQF 2496).

KCP is steadfast in its belief that readmissions are an important outcome to measure, but we believe that the recent removal of NQF endorsement, and that a number of our longstanding concerns about reliability, validity, and specification issues remain unaddressed, make the SRR inappropriate for use in the penalty-based QIP. We detail these concerns in the following sections.

- NQF Endorsement Withdrawn. NQF removed endorsement from the SRR in November 2020, primarily because of inadequate measure validity (see following section). NQF is recognized as a voluntary consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget Circular A-119.

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NQF's formal Consensus Development Process (CDP) to evaluate and endorse healthcare performance measures is specifically designed to call for input and to carefully consider the interests of stakeholder groups from across the healthcare industry. This carefully constructed CDP plays an integral role in helping the MAP assess the suitability of measures for use in a variety of federal quality and performance programs—indeed, MAP's formal Measure Selection Criteria (MSC) indicate that measures that have been evaluated and denied NQF endorsement or have had endorsement removed "are not suitable and should be removed from federal programs" (MSC1, Sub-criterion 1.3). We agree with this guidance. A measure from which NQF endorsement has been removed no longer has the support of the relevant stakeholder community and should not be deployed in federal accountability programs, particularly when tied to reimbursement.

• Validity. Consistent with the Admissions/Readmissions Standing Committee's recent recommendation against continued endorsement, KCP has significant concerns with the SRR's validity. The Standing Committee did not pass the SRR on Validity, a "must pass" criterion. Notably, while in the expected directions, correlations with other outcomes measures were demonstrably weak, with a rho of 0.39 with the Standardized Hospitalization Ratio (SHR), 0.10 with the Standardized Mortality Ratio (SMR), and 0.04 with the long-term catheter rate measure. We thus concur with the Standing Committee's conclusion that the measure is not a valid representation of the quality of care provided by dialysis facilities in this regard. KCP also notes that validity testing yielded a c-statistic for the SHR of 0.6768. 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. We are thus concerned the model will not adequately discriminate performance—particularly that smaller units might look worse than reality.

•Reliability. Even more concerning in our view is the metric's extremely poor reliability. The overall Inter-Unit Reliability (IUR) for this iteration of the SRR was found to be 0.35, such that nearly two-thirds of a facility's score on the measure can be attributed to noise and not signal. This value also represents a sizeable decline from the 2009 IUR of 0.55. Though we recognize the characterization also depends on the analytic method, we again note a reliability statistic less than 0.50 is considered "unacceptable." KCP believes CMS should implement the measure adjusted to yield a reliable result (reliability statistic of 0.70 or greater), consistent with how the NQF bases its evaluation of measures and more generous than the literature. We further note here that CMS did not provide the Standing Committee reliability data stratified by facility size because it "is not required" by NQF. Prior SRR testing indicated notably poorer reliability for small facilities (defined in 2009 as facilities with fewer than 70 patients for the SRR), with an IUR of 0.46 compared to the overall IUR of 0.55. Given this history and the notable decline in the overall IUR since the measure was last reviewed by NQF, we believe it is imperative that CMS provide the most recent SRR reliability results stratified by facility size. Absent that information, we submit that the demonstrably unreliable SRR, 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.

- Medicare Advantage (MA) Patients. Data provided to the NQF Standing Committee by

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CMS 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. Such geographic variation compromises the validity of the measures if MA patients are not accurately accounted for in the QIP metrics. Specifically, without changes to the current specifications, the evolving patient mix will introduce significant bias into measure calculations that could affect results for facilities with either very low or high MA patient populations. Recognizing this, KCP concurs with CMS on the need to change measure specifications to accommodate the increase in MA patients and to avoid disparities in performance due to geography. KCP strongly believes, however, that greater transparency is required by CMS as it updates relevant measures and urges CMS to perform a sensitivity analysis of SRR performance with and without MA patients and to make the results publicly available. Such data will provide an opportunity for KCP and other stakeholders to offer potential, evidence-based mitigation strategies (e.g., a model that accounts for both populations, use of risk coefficients, as necessary).

CMS also should perform an analysis of risk model fit under the previous approach and the new in-patient-claims-only approach intended to accommodate the increasing MA population; currently we are unable to assess whether model fit improved or worsened with this approach. In particular, KCP is concerned that limiting comorbidity data to inpatient claims might skew the models towards a sicker population, and that such a skew might reflect unfavorably on facilities that successfully keep readmission 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 and readmission 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.

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.530.9524).

Sincerely,

Kidney Care Partners

Kidney Care Partners
1.Akebia Therapeutics, Inc.
2.American Kidney Fund, Inc.
3.American Nephrology Nurses Association
4.American Renal Associates
5.American Society of Nephrology
6.American Society of Pediatric Nephrology
7.Amgen, Inc.
8.Ardelyx
9.AstraZeneca
10.Atlantic Dialysis Management Services, LLC

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11.Baxter International, Inc.
12.B. Braun Medical, Inc.
13.Cara Therapeutics, Inc.
14.Centers for Dialysis Care
15.DaVita, Inc.
16.Dialysis Patient Citizens, Inc.
17.DialyzeDirect
18.Fresenius Medical Care North America
19.Fresenius Medical Care Renal Therapies Group
20.Greenfield Health Systems
21.Kidney Care Council
22.North American Transplant Coordinators Organization
23.Nephrology Nursing Certification Commission
24.Otsuka America Pharmaceutical, Inc.
25.Renal Physicians Association
26.Renal Support Network
27.Rockwell Medical
28.Rogosin Institute
29.Satellite Healthcare, Inc.
30.U.S. Renal Care, Inc.
31.Vertex Pharmaceuticals
32.Vifor Pharma Ltd.

Kidney Care Partners (KCP) appreciates the opportunity to comment on the Measures Under Consideration (MUCs) for use in Federal Health Programs for the Measure Applications Partnership (MAP) 2022 Pre-Rulemaking Cycle. 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 single measure proposed by the Centers for Medicare and Medicaid Services (CMS) for use in the ESRD Quality Incentive Program (QIP)—the Standardized Readmission Ratio for Dialysis Facilities (SRR, previously NQF 2496).

KCP is steadfast in its belief that readmissions is an important outcome to measure, but we support MAP's recommendation of "Do Not Support for Rulemaking" for the SRR. We believe that the recent removal of NQF endorsement, combined with our longstanding concerns about measure reliability, validity, and numerous specification issues that remain unaddressed, make the SRR inappropriate for use in the penalty-based QIP. We detail these concerns in the following sections.

• NQF Endorsement Withdrawn. NQF removed endorsement from the SRR in November 2020, primarily because of inadequate measure validity (see following section). NQF is recognized as a voluntary consensus standards-setting organization as defined by the National Technology Transfer and Advancement Act of 1995 and Office of Management and Budget Circular A-119. NQF's formal Consensus Development Process (CDP) to evaluate and endorse healthcare performance measures is specifically designed to call for input and to carefully consider the interests of stakeholder groups from

across the healthcare industry. This carefully constructed CDP plays an integral role in helping the MAP assess the suitability of measures for use in a variety of federal quality and performance programs—indeed, MAP's formal Measure Selection Criteria (MSC) indicate that measures that have been evaluated and denied NQF endorsement or have had endorsement removed "are not suitable and should be removed from federal programs" (MSC1, Sub-criterion 1.3). We agree with this guidance. A measure from which NQF endorsement has been removed no longer has the support of the relevant stakeholder community and should not be deployed in federal accountability programs, particularly when tied to reimbursement.

• Validity. Consistent with the Admissions/Readmissions Standing Committee's recent recommendation against continued endorsement, KCP has significant concerns with the SRR's validity. The Standing Committee did not pass the SRR on Validity, a "must pass" criterion. Notably, while in the expected directions, correlations with other outcomes measures were demonstrably weak, with a rho of 0.39 with the Standardized Hospitalization Ratio (SHR), 0.10 with the Standardized Mortality Ratio (SMR), and 0.04 with the long-term catheter rate measure. We thus concur with the Standing Committee's conclusion that the measure is not a valid representation of the quality of care provided by dialysis facilities in this regard.

• Reliability. Even more concerning in our view is the metric's extremely poor reliability. The overall Interunit Reliability (IUR) for this iteration of the SRR was found to be 0.35, such that nearly two-thirds of a facility's score on the measure can be attributed to noise and not signal. This value also represents a sizeable decline from the 2009 IUR of 0.55. Though we recognize the characterization also depends on the analytic method, we again note a reliability statistic less than 0.50 is considered "unacceptable." KCP believes CMS should implement the measure adjusted to yield a reliable result (reliability statistic of 0.70 or greater), consistent with how the NQF bases its evaluation of measures and more generous than the literature.

We further note here that CMS did not provide the Standing Committee reliability data stratified by facility size because it "is not required" by NQF. Prior SRR testing indicated notably poorer reliability for small facilities (defined in 2009 as facilities with fewer than 70 patients for the SRR), with an IUR of 0.46 compared to the overall IUR of 0.55. Given this history and the notable decline in the overall IUR since the measure was last reviewed by NQF, we believe it is imperative that CMS provide the most recent SRR reliability results stratified by facility size. Absent that information, we submit that the demonstrably unreliable SRR, 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.

• Medicare Advantage (MA) Patients. Data provided to the NQF Standing Committee by CMS 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. Such geographic variation compromises the validity of the measures if MA patients are not accurately accounted for in the QIP metrics. Specifically, without changes to the current specifications, the evolving patient mix will introduce significant bias into measure calculations that could affect results for facilities with either very low or high MA patient populations. Recognizing this, KCP concurs with CMS on the need to change measure specifications to

accommodate the increase in MA patients and to avoid disparities in performance due to geography. KCP strongly believes, however, that greater transparency is required by CMS as it updates relevant measures and urges CMS to perform a sensitivity analysis of SRR performance with and without MA patients and to make the results publicly available. Such data will provide an opportunity for KCP and other stakeholders to offer potential, evidence-based mitigation strategies (e.g., a model that accounts for both populations, use of risk coefficients, as necessary).

CMS also should perform an analysis of risk model fit under the previous approach and the new in-patient-claims-only approach intended to accommodate the increasing MA population; currently we are unable to assess whether model fit improved or worsened with this approach. In particular, KCP is concerned that limiting comorbidity data to inpatient claims might skew the models towards a sicker population, and that such a skew might reflect unfavorably on facilities that successfully keep readmission 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 and readmission 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.

KCP again thanks you for the opportunity to comment on this important work. If you have any questions, please do not hesitate to contact Lisa McGonigal, MD, MPH (lmcgon@msn.com or 203.530.9524).

Sincerely,

Kidney Care Partners

Johnson & Johnson

Johnson & Johnson does not agree with the MAP's recommendation for this measure. Johnson & Johnson recognizes both MAP and the NQF Admissions and Readmissions Committee's concerns with this measure's scientific acceptability on validity and encourages the MAP to offer a mitigation opportunity for the measure steward to revise the specifications to resolve NQF's concerns. The measure is currently included in the ESRD QIP, which demonstrates its applicability to improving gaps in care coordination or transitions of care for a vulnerable population. Johnson & Johnson supports rulemaking for this measure to encourage facilities to implement initiatives to practice discharge methods that would result in successful discharge.

Evidence suggests that pre- and post-discharge interventions by dialysis providers may reduce the risk of unplanned readmissions within the ESRD chronic dialysis population. By holding renal dialysis facilities accountable for ensuring successful discharges of patients, decision-making related to patient discharge (e.g., ensuring patients are appropriately vaccinated) will be in the patient's best interest.

Johnson & Johnson supports measures that promote management of care for vulnerable dialysis patients to avoid unnecessary readmissions. We further support standardization of clinical activities that can be shared with providers to reduce readmissions (e.g., vaccination to avoid infection).

American Hospital Association

The AHA agrees with the MAP's recommendation of Do Not Support for rulemaking. This measure failed

endorsement in the Spring of 2020 as it did not prove scientifically valid following review by the Scientific Methods Panel. Any measure with such statistical and scientific inadequacy is inappropriate for use in federal programs.

Association of American Medical Colleges (AAMC)

The Hospital MAP did not support this readmission measure (MUC2021-101) for rulemaking for the End-Stage Renal Disease (ESRD) Quality Improvement Program. The AAMC agrees with the MAP's initial recommendation. This measure did not pass scientific acceptability for validity and was not endorsed by the NQF when reviewed in Spring 2020. The NQF Scientific Methods Panel did not pass the measure on review of validity due to concerns regarding the adequacy of the measure correlations presented for validity testing. The NQF Standing Committee for Admissions and Readmissions reviewed the Panel's findings and upheld their rating, ultimately failing endorsement on the ground on validity. The AAMC continues to believe that measures must be endorsed as valid and reliable prior to inclusion in federal quality reporting and performance programs.

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Hospital-Acquired Condition Reduction Program (HACRP)

MUC 2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program

Hospital-Acquired Condition Reduction Program, Medicare Promoting Interoperability Program for Hospitals, Hospital IQR Program, PPS-Exempt Cancer Hospital Quality Reporting Program, Long-Term Care Hospital Quality Reporting Program, Inpatient Rehabilitation Facility Quality Reporting Program, Skilled Nursing Facility Quality Reporting Program

Workgroup

Hospital

Measure Description

This measure tracks the development of new Clostridioides difficile infection among patients already admitted to healthcare facilities, using algorithmic determinations from data sources widely available in electronic health records. This measure improves on the original measure by requiring both microbiologic evidence of C. difficile in stool and evidence of antimicrobial treatment.

Numerator

Healthcare-Associated Clostridioides difficile Infection (HA-CDI):
Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.
HA-CDI 1: must meet BOTH A & B.

A. Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.
B. Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

HA-CDI 2: must meet BOTH A & B.

A. Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.
B. Administration of oral or intravenous metronidazole within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

Numerator Exceptions

Excluding well baby-nurseries and neonatal intensive care units (NICU).

Denominator

The expected number of HA-CDI based on predictive models using facility- and patient care location data as predictors.

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Denominator Exclusions
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count
Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions
Under investigation, subject to change.

State of development
Specification

State of Development Details
The measure stewards have partnered with several research groups to evaluate HA-CDI in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing.

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Infectious disease

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1) Microbiology records of stool tests for C. difficile, typically from an EHR laboratory information system.
2) Medication administration records (eg. antimicrobial administration), from EHR.
3) Administration records, non-claims (eg. date of admission, discharge, patient location).

The HA-CDI measure requires linking relevant stool microbiological test results with applicable antimicrobial administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

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What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

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If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
MUCFIFTEEN-533: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

How will this measure be distinguished from other similar and/or competing measures?
The current NHSN measure is based on laboratory results, and C. difficile is typically diagnosed using non-culture based diagnostic tests which have wide variation in sensitivity and in rates of false positives. Creating a surveillance definition that more closely approximates the disease-state requires incorporating clinical decision-making into the measure. The updated measure includes not only the lab test for C. difficile but also the use of an antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the limited and particular therapies used for infections due to C. difficile.

How will this measure add value to the CMS program?
This new measure increases the clinical validity of original measure, and therefore more accurately reflect the presence of clinical infection and quality measurement.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

C. difficile caused 159,463 infections among hospitalized US patients in 2019. (1) Robust surveillance combined with incentives from value-based purchasing resulted in a reduction of 42% between 2015 and 2019 in acute-care hospitals. (1) Further improvements are possible, but aspects of the existing surveillance definition complicate the external reception of the measure and create unintended consequences regarding testing and treatment practices. (2, 3) These issues also challenge the ability to track trends in true infections as organizations alter their practices. Validation studies performed from 2013 -2106 by 6 different states, suggest that the negative predictive value of the metric is low at ~59% indicating that, in addition to potential manipulation of testing practices, many cases are being missed in the reporting process. (4) To address these concerns, CDC's National Healthcare Safety Network (NHSN) proposes a new measure that promotes further improvements in care for patients and reduces unintended consequences.

Creating an improved surveillance definition that more closely approximates the disease-state requires incorporating use of therapy as a proxy for clinical decision-making into the measure. To that end, this new NHSN measure includes not only the lab test for C. difficile but also the use of a specific antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the specific therapies used for infections due to C. difficile. (5)

References

1. Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI
2. Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458
3. Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf
4. Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN
5. McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

Evidence that the measure can be operationalized

There is a proven track record for CMS to obtain this data from NHSN which currently shares facility-level CDI SIRs for hospital IQR program.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

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Evidence of Performance Gap
Analysis forthcoming

Unintended Consequences
It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection. It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score
To be determined.

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HA-CDI event, the mean unadjusted cost is ~$50,000 (median $27,000). As an unadjusted, unmatched comparison group, hospitalizations with only a negative stool test for C. difficile had an average cost of ~$26,000 (median ~$11,000). (Unpublished data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019.

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Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
No

If yes, choose all methods that obtained clinician and/or provider input
N/A

Total Number of Clinicians/Providers Consulted
N/A

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
N/A

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

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If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs and EIP projects summer 2021.

Measure performance – Type of Score
Ratio

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Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

HA-CDI performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).

Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HA-CDI events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HA-CDI events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HA-CDI events for the facility using the negative binomial regression model.
3. Divide the number of observed HA-CDI events (1 above) by the number of expected HA-CDI events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HA-CDI events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient

case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HA-CDI events for the facility
2. Obtain the adjusted number of observed HA-CDI for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HA-CDI events
4. Obtain the expected number of HA-CDI events
5. Divide the total number of adjusted HA-CDI events (3 above) by the predicted number of HA-CDI events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable

See methods above for calculation of SIR and ARM.

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Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
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Long-Term Measure Steward
Centers for Disease Control and Prevention

Long-Term Measure Steward Contact Information
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800-232-4636

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes
Justification and Notes: The Measure Under Consideration calculates the observed number of Healthcare-Associated Clostridioides difficile Infections (HA-CDI) at a healthcare facility, divided by the number of infections expected based on facility characteristics. This measure would update a very similar measure currently included in the Hospital-Acquired Condition Reduction Program (HACRP), NQF#1717, by only counting cases where there was evidence of both a positive test and treatment. Measuring healthcare-associated infections remains a high priority for the HACRP, and Patient Safety is a Meaningful Measures 2.0 area.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes:
After several years of implementation of HA-CDI quality measures, 48 percent decrease in reported HA-CDIs was observed from 2015-2020. This indicates hospitals have successfully implemented initiatives,

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such as CDC guidelines for hand hygiene, that are reducing infection rates. This measure is intended to capture HA-CDI infections more precisely than the existing measure by only counting those infections among inpatients that both a position laboratory test and evidence of an antimicrobial agent administered to the patient two days before or after the positive test result.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: HA-CDI infections are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDI infections were reported to the CDC. CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures. According to NHSN reports, in 2020 the 20th percentile of performance for acute care hospitals was .182 infections observed/expected, compared to an 80th percentile performance of .762 infections observed/expected, indicating a substantial range in performance

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes This measure would replace a similar, existing measure of HA-CDI infections observed/expected already included in the HACRP. Versions of the same HA-CDI monitoring measure are also currently in use for quality reporting programs for long term care hospitals and inpatient rehabilitation facilities.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: All data elements required to calculate the measure are available in defined fields in electronic data. A similar HA-CDI measure currently implemented in other programs has been successfully submitted by thousands of acute care hospitals for several years.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: This measure is a specification update to an existing NQF-endorsed measure, #1717. The revised specifications have not been submitted to NQF for endorsement, and reliability and validity testing has not been finalized.

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?

Yes/No: No

Justification and Notes: The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test for CDI AND a treatment administered. This update is intended to mitigate instances where a facility or provider might be incentivized not to test for a suspected HA-CDI.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

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Impact Act Domain
Yes/No: N/A
Justification: N/A

Hospice High Priority Areas
Yes/No: N/A
Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.6
1 – 0 votes
2 – 1 votes
3 – 2 votes
4 – 8 votes
5 – 0 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.4
1 – 0 votes
2 – 2 votes
3 – 7 votes
4 – 8 votes
5 – 0 votes

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Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set? This Measure Under Consideration would modify the existing HA-CDI surveillance measure in the Hospital-Acquired Condition Reduction Program (HACRP), by only counting cases where there was evidence of both a positive test and treatment. This may mitigate potential unintended consequences from the current measure's design, counting a case based on a positive test only, which may have led to a historical under-counting of observed HA-CDI. This updated measure is consistent with the program's priority to measure healthcare associated infections, and the Patient Safety Meaningful Measures 2.0 area.

Summary: What is the potential impact of this measure on quality of care for patients?
An HA-CDI infection has serious potential consequences for patients, including death. Nearly 114,000 HA-CDI were reported to the CDC in 2020. The performance of long-term care hospitals on the existing HA-CDI measure shows considerable variation in performance: the 20th percentile of performance for acute care hospitals was .182 infections observed/expected, compared to an 80th percentile performance of .762 infections observed/expected. Nevertheless, this performance has improved by 48 percent over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines.

MAP conditionally supported the measure for rulemaking pending NQF endorsement and resolution of duplication concerns by CMS.

Section 3: Public Comments

Society for Healthcare
Would support reviewing in the NQF process

Federation of American Hospitals
The Federation of American Hospitals (FAH) supports the further refinements to this measure but recommends that the measure with these changes is tested and endorsed by the National Quality Form prior to implementation in this program. In addition, the Centers for Medicare and Medicaid Services must address the duplicate reporting of the measure results as these revisions are implemented in either program. The potential for misleading and/or inaccurate information must be avoided at all costs. As a result, the FAH requests that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

Premier, Inc.
Premier conditionally supports adoption of the measure. The refined measure improves on existing measures by requiring both evidence of an infection and treatment, which will help to exclude cases resulting from colonization and improve clinical validity of the measure. However, we are concerned that this measure is similar to the existing CDI measure and that adoption will duplicate measurement. We would encourage CMS to clarify a timeline for replacing the existing CDI measure with this refined

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measure. Additionally, CMS should not move forward with the measure until it has received endorsement.

The Society for Healthcare Epidemiology of America
Do you recommend this measure?

Yes

BD
Thank you for the opportunity to provide information and areas for potential improvement regarding the 2021 MAP Measures Under Consideration. As one of the largest global medical technology companies in the world, BD is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company develops innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare providers. BD helps clinicians enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care.

BD is supportive of the NHSN Healthcare-associated Clostridioides difficile Infection Outcome Measure. Healthcare-associate Clostridioides difficile (HA-CDI) currently is a lab and time-based definition. Clinicians know that there is a discrepancy between the existing NHSN definition, which is purely lab based, and the reality that this entity is a clinical diagnosis (i.e., a combination of laboratory, history, physical exam and sometimes imaging and biopsy findings). Thus, there is likely room for improvement in how HA-CDI is reported.

With the advent of Clostridioides difficile (CDI) PCR, practices for testing and treatment of CDI have evolved. PCR technology alone can be hypersensitive(1) due to detection of genetic fragments of inactive or partial remnants of dead organism, and therefore the testing for HA-CDI has evolved to as complex as two or even in some cases three-tiered testing(2) to help improve specificity of reporting. The varied practices for testing of HA-CDI therefore makes for varied sensitivity and specificity if relying solely on a lab-based identification.

The proposal put forth, by tethering laboratory-identified CDI with a therapeutic anti-CDI medication will likely help resolve this conundrum by including the important data element of a therapeutic drug. The specificity with this “intent to treat” signal should increase and help improve the landscape of identifying clinically relevant HA-CDI cases. Studies on HA-CDI have shown that older age, community burden of CDI and length of stay may increase HA-CDI burden.(3) Thus, a certain amount of risk adjustment would be preferable as well.

In summary, we support the proposed new NHSN definition of Healthcare-associated Clostridioides difficile Infection Outcome Measure. Barriers to implementation may include the component of medication (i.e., therapeutic anti-CDI drug); however, with the established success of the NHSN AU Module and uploading antimicrobial use, this perceived barrier may be less pervasive as more healthcare centers become experienced with electronic medical record data. The addition of a therapeutic CDI medication should help with specificity issues when using a lab only based reporting metric. Finally, future applications of this measure may include greater visibility to certain antimicrobials associated with higher risk for CDI.(3) With more accurate designation of HA-CDI, antimicrobial

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stewardship programs may be able to better designate target goals for HA-CDI mitigation within their facilities.

Sincerely,

Kalvin Yu, MD, FIDSA

Vice President, Medical & Scientific Affairs, US Region

BD

References:

(1) Sara Y. Tartof, Kalvin C. Yu, Rong Wei, Hung Fu Tseng, Steven J. Jacobsen, Gunter K. Rieg,

Incidence of Polymerase Chain Reaction–Diagnosed Clostridium difficile in a Large High-Risk Cohort, 2011-2012,

Mayo Clinic Proceedings, Volume 89, Issue 9,2014,Pages 1229-1238,ISSN 0025-6196,

https://doi.org/10.1016/j.mayocp.2014.04.027.

(2) L Clifford McDonald, Dale N Gerding, Stuart Johnson, Johan S Bakken, Karen C Carroll, Susan E Coffin, Erik R Dubberke, Kevin W Garey, Carolyn V Gould, Ciaran Kelly, Vivian Loo, Julia Shaklee Sammons, Thomas J Sandora, Mark H Wilcox, Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA), Clinical Infectious Diseases, Volume 66, Issue 7, 1 April 2018, Pages e1–e48, https://doi.org/10.1093/cid/cix1085

(3) Tabak, Y., Srinivasan, A., Yu, K., Kurtz, S., Gupta, V., Gelone, S., . . . McDonald, L. (2019). Hospital-level high-risk antibiotic use in relation to hospital-associated Clostridioides difficile infections: Retrospective analysis of 2016–2017 data from US hospitals. Infection Control & Hospital Epidemiology, 40(11), 1229-1235. doi:10.1017/ice.2019.236

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MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital-Acquired Condition Reduction Program, Medicare Promoting Interoperability Program for Hospitals, Hospital IQR Program, PPS-Exempt Cancer Hospital Quality Reporting Program

Workgroup
Hospital

Measure Description
This measure tracks the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in electronic health records. This measure includes many healthcare-associated infections not currently under surveillance by the Center for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN). Ongoing surveillance also requires minimal data collection burden for users.

Numerator
Observed number of Hospital-Onset Bacteremia & Fungemia (HOB) events, defined below:

Must meet Bacteremia OR Fungemia criteria (BFC), AND Antimicrobial treatment criteria (ATC).

Bacteremia OR Fungemia criteria (BFC):

Patient of any age has a recognized bacterial or fungal pathogen from a blood specimen collected on the 3rd calendar day of admission or later (where the date of admission to an inpatient location is calendar day 1). The pathogen must not be included on the NHSN common commensal list, and meet EITHER of the following criteria:

1. Pathogen identified by culture of one or more blood specimens, OR
2. Pathogen identified to the genus or species level by non-culture based microbiologic testing (NCT) methods. Note: if blood is collected for culture within 2 days before, or 1 day after the NCT disregard the result of the NCT and use only the result of the CULTURE to make a BFC determination. If no blood is collected for culture within this time period, use the result of the NCT for BFC determination.

Antimicrobial Treatment Criteria (ATC):

A patent must have been administered at least 1 dose of an intravenous or oral (including all enteral routes) antimicrobial in the window period extending 2 calendar days before and 2 calendar days after the date of blood specimen collection for BFC. The date of blood specimen collection is day 0.

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Furthermore, if the patient had Bacteremia only antibiotics are eligible to meet the ATC criteria. Similarly, if the patient has Fungemia, only antifungals are eligible to meet ATC criteria. If a patient has both Bacteremia and Fungemia, then either an antibiotic or antifungal can meet the ATC criteria.

Numerator Exceptions

1) Previous matching Present on Admission Bacteremia or Fungemia

If a patient meets BFC but also had a pathogen matching to the same species or genus level identified from a blood specimen by culture or NCT that was collected in the Present on Admission (POA) window, defined as hospital calendar day 2 or earlier (where calendar date of admission to an inpatient location is day 1), then this BFC is excluded from the HOB measure.

If multiple pathogens are identified from the same blood culture or NCT, then a match of any of those pathogens to a POA blood pathogen is sufficient to exclude the BFC from the HOB measure.

2) Previous HOB event

A patient with a previous HOB event is excluded from additional HOB events during the same hospital admission.

Denominator

The expected number of HOB events based on predictive models using facility- and patient care location data as predictors.

Denominator Exclusions

Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts. Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions

Under investigation, subject to change.

State of development

Specification

State of Development Details

Specification: The measure stewards have partnered with several research groups to evaluate HOB in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing:

A) Hospital-Onset Bacteremia & Fungemia Preventability Evaluation (HOPE): Two components

1. Evaluation of sources and preventability of HOB events in ~2400 adult and pediatric patients across 13 hospitals. Results expected summer/fall 2021.
2. HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes, and risk factors for HOB in Cerner Healthfacts and Premier Healthcare Databases (500 hospitals, 18,000,000 admissions). Results expected summer 2021.

B) Becton Dickinson: HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes and cost, risk factors, and surveillance feasibility for HOB in 271 hospitals, 8,000,000 admissions. Results

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expected summer/fall 2021.

C) Veterans Affairs: HOB definition sensitivity analysis, chart review validation, evaluation of epidemiology, surveillance feasibility in 142 hospitals, 1,700,000 admissions. Results expected summer 2021.

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Infectious disease

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1. Microbiology records of blood cultures and NCT, typically from an EHR laboratory information system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

The HOB measure requires linking relevant microbiological test results for blood cultures and NCT with applicable antimicrobial administration records from the medication administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

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CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
MUC2019-19: "National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection Outcome Measure"

MUCFIFTEEN-532MRSA: "National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure"

How will this measure be distinguished from other similar and/or competing measures?
The HOB outcome measure collects the number of bloodstream infections that occur during hospitalization (and not present on admission) due to a broad range of pathogenic bacteria and fungi (in contrast to the narrower MRSA measure), and regardless of whether the infection was attributable to a central line or device (in contrast to the narrower CLABSI measure).

Furthermore, the inclusion of evidence of antimicrobial treatment for the HOB measure increases the clinical validity of the measure by acting as a proxy for true infections requiring treatment from the provider. This component may become more valuable as emerging non-culture based microbiologic testing (NCT) become more ubiquitous. These tests may have increased false positive signals or could detect pathogen genetic material that may not correspond to live pathogens causing an ongoing bacteremia or fungemia. Thus, requiring evidence of antimicrobial treatment serves as a proxy for the clinical interpretation of infection by the provider.

How will this measure add value to the CMS program?
The HOB outcome measure includes most to nearly all central-line associated bloodstream infections and MRSA bacteremias, and many more bloodstream infections that cause healthcare associated infections but are not currently under surveillance for quality measurement. Preliminary data suggests a substantial percentage of HOB events are preventable under current infection prevention standards, and we anticipate that use of an HOB outcome measure will encourage innovation to identify new

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methods for reducing these infections.

Furthermore, the HOB measure uses an algorithmic approach to determine events, thus reducing regular data collection burden and subjectivity from event determination. “HOB surveillance could inform broad measures to improve infection control in conjunction with other HAI data, potentially resulting in measurably improved patient outcomes. HOB data collection and reporting burden would likely be low given the ubiquity and functionality of current EHRs, in contrast to NHSN CLABSI and other measures that call for substantial investments of time and effort in manual reviews of healthcare records.” (1)

References:

1) Dantes et al. Hospital epidemiologists’ and infection preventionists’ opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Multiple justification studies are underway.

An HOB measure is viewed favorably among subject matter experts and users. A survey of 89 researchers in the Society for Hospital Epidemiology of America (SHEA) Research Network found that “Among the majority of SHEA Research Network respondents, HOB is perceived as preventable, reflective of quality of care, and potentially acceptable as a publicly reported quality metric.” Furthermore, “Given a choice to publicly report central-line-associated bloodstream infections (CLABSIs) and/or HOB, 57% favored reporting either HOB alone (22%) or in addition to CLABSI (35%) and 34% favored CLABSI alone. (1)

References

1) Dantes et al. Hospital epidemiologists’ and infection preventionists’ opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540.

Evidence that the measure can be operationalized

The HOB measure leverages sources of data, primarily microbiology and medication administration data, that are already used for many existing CDC National Healthcare Safety Network (NHSN) measures and reported to CMS on a quarterly basis.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

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Feasibility of Data Elements
ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap
Interim and preliminary analysis from the HOPE study with approximately half the data collected shows approximately 41% of HOB events were considered preventable after expert review. Final results expected summer/fall 2021.

Unintended Consequences
It is possible that providers and facilities may be discouraged from ordering blood cultures or NCT among patients that are later into their hospitalization when they suspect an infection.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score
To be determined.

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HOB event, the mean unadjusted cost is ~$83,000 (median $44,000). As an unadjusted, unmatched comparison group, hospitalizations with negative blood cultures had an average cost of ~$45,000 (median $26,000). (Data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

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Year of Cost Literature Cited
October 2015 through June 2019

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys

Total Number of Clinicians/Providers Consulted
76

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
41

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Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs project summer 2021

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs project summer 2021

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs project summer 2021

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

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Validity Testing Sample Size
Planned for Veterans Affairs project summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs project summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs project summer 2021.

Measure performance – Type of Score
Ratio

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
HOB performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).

Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HOB events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HOB events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HOB events for the facility using the negative binomial regression model
3. Divide the number of observed HOB events (1 above) by the number of expected HOB events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HOB events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HOB events for the facility
2. Obtain the adjusted number of observed HOB for the facility using a Bayesian posterior

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distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.

3. Total these numbers for an observed HOB events
4. Obtain the expected number of HOB events
5. Divide the total number of adjusted HOB events (3 above) by the predicted number of HOB events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable
See description of SIR and ARM above.

Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
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Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

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Section 2: Preliminary Analysis – MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. This measure addresses the Hospital-Acquired Condition Reduction Program (HACRP)'s measurement priorities, and the specifications are consistent with the HACRP requirements for inclusion. Moreover, the measure focus corresponds to the Patient Safety Meaningful Measures 2.0 area. There are two measures currently included in HACRP, whose measure result would, in part, be reflected in this proposed measure: (1) the NHSN MRSA bacteremia measure, and (2) the NHSN CLABSI measure. However, the proposed measure vastly increases the number of applicable microorganisms and attributable causes that would be captured in the measure.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: There is evidence that the HOB tracked by this outcome measure can be prevented by hospitals; one 2017 study by Dantes et al estimated that 49% of HOB infections were potentially preventable, and a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists estimated that 50 percent or more of HOBs could be prevented, with a variety of hospital practices identified that could reduce HOBs. In an unpublished analysis of healthcare data by the measure submitter, hospitalizations with an HOB were found to be nearly twice as expensive as those without (average cost of $83,000 compared to $45,000).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: HOB are common infections, especially relative to other infections currently measured in quality reporting programs: for example, a 2015 study by Rock et al found that HOB infections were 17 times as likely to be observed in an ICU compared to CLABSI infections. The same study concluded that a change in HOB rate has a greater power to discriminate between ICU performance than CLABSI rates. Contracting an HOB leads to a greatly increased risk of mortality, as found by Lambert et al, 2011. The developer also cites preliminary results from the HOPE study analysis in which approximately 41 percent of HOB events were considered preventable after expert review. The developer notes that final study results are expected summer/fall 2021. Although performance data for this measure are not yet available, a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists found that 54 percent agreed that the measure concept would reflect quality of care at a hospital.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: There are two measures currently included in HACRP, whose measure result

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would, in part, be reflected in this proposed measure: (1) the NHSN MRSA bacteremia measure, and (2) the NHSN CLABSI measure. However, the proposed measure vastly increases the number of applicable microorganisms and attributable causes that would be captured in the measure. For example, one 2015 study by Rock et al found that HOB infections were 17 times as likely to be observed in an ICU compared to CLABSI infection, leading to additional discriminatory power for the measure result. Likewise, a 2017 study by Dantes et al estimated that just 10 percent of all bacteremia and fungemia observed across three academic medical centers were *s. aureus*. Therefore, adding this measure to the HACRP program would represent adding surveillance events that are mostly not captured by existing measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: All data elements are available in defined electronic fields; no data abstraction is required.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is specified for the appropriate care setting, level of analysis, and patient population. However, no reliability or validity testing of the measure result has been conducted, and the measure has not been reviewed for endorsement by NQF.

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?

Yes/No: Yes

Justification and Notes: Although the measure has not been implemented or tested in a healthcare facility, one possible unintended consequence that the developer identified is that the measure may discourage providers and hospitals from testing patients where they suspect a bacteremia or fungemia infection.

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

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Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.8
1 – 0 votes
2 – 1 votes
3 – 1 votes
4 – 8 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.4
1 – 0 votes
2 – 2 votes
3 – 6 votes
4 – 9 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?

This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. This measure addresses Hospital-Acquired Condition Reduction Program (HACRP)'s measurement priorities, and the specifications are consistent with the HACRP requirements for inclusion. Although there is some overlap with the existing CLABSI and MRSA measures in the program set, adding this measure to the HACRP program would add surveillance of infections that are mostly not captured by either of those measures.

Summary: What is the potential impact of this measure on quality of care for patients?

This Measure Under Consideration tracks a group of very common, and potentially lethal, hospital-acquired infections. Hospitalizations where these conditions were identified were nearly twice as expensive as the average hospital stay, indicating high resource utilization needed to treat these conditions. Despite the common and costly nature of these infections, studies and surveys estimate that nearly half of these infections are preventable by the hospital. Incentivizing the adoption of infection control practices that would reduce the incidence of these conditions would present a substantial

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benefit to both patients and the health care system.

MAP conditionally supported the measure for rulemaking pending NQF endorsement.

Section 3: Public Comments

The Society for Healthcare Epidemiology of America

Yes; support for inclusion in the program

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports measures that ensure patient safety and reduction of infections for individuals receiving care during an inpatient stay but measures must be based on robust evidence and produce reliable and valid results. This measure does not currently meet any of these minimum requirements nor has it received endorsement by the National Quality Forum. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

Premier, Inc.

Premier conditionally supports adoption of this measure. While we agree that this measure addresses some healthcare-associated infections not currently under NHSN surveillance, we are concerned that it may duplicate existing measurement under the HAC Reduction Program (e.g., CLABSI and MRSA measures). We encourage CMS to develop a strategy that ensures broader surveillance of HAIs without increasing burden on hospitals or duplication of existing efforts. Additionally, CMS should not move forward with the measure until it has received endorsement.

Society of Hospital Medicine

We agree that preventing avoidable hospital-onset bacteremia & fungemia is an important goal, but have concerns about potential overlap of this measure with the existing CLABSI measure and the overall preventability of non-central line associated bacteremia and fungemia in the hospital. This measure needs to be better differentiated from other measures and targeted on preventable events. We also ask the MAP to consider how this measure may impact appropriate use of testing and appropriate use of antimicrobials.

We are also concerned that the rationale lacks significant studies or evidence for the measure, notably ones identifying the potential for preventability of HOB. We ask the MAP to consider waiting on this measure until more research and evidence supporting the measure is available and potential overlaps with other existing measures are addressed.

Johnson & Johnson

Johnson & Johnson agrees with the MAP's recommendation of conditional support for this measure. This measure encourages hospitals to take precautions that prevent hospital-onset bacteremia and fungemia. By holding hospitals accountable for the development of new bacteremia and fungemia infections, this measure promotes patient safety, improves quality outcomes and seeks to contain avoidable infections and excess costs. In general, Johnson & Johnson supports measures that incentivize management and reduction of hospital-onset infections and addresses Hospital-Acquired Condition Reduction Program measurement priorities.

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BD

Thank you for the opportunity to provide information and areas for potential improvement regarding the 2021 MAP Measures Under Consideration. As one of the largest global medical technology companies in the world, BD is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company develops innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for healthcare providers. BD helps clinicians enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care.

BD is supportive of the NHSN Hospital-Onset Bacteremia & Fungemia Outcome Measure to be used for HACRP and other CMS programs. The development of the Central Line-associated Bloodstream Infection (CLABSI) metric resulted in considerable improvements in CLABSI rates since its introduction in 2015 and raised awareness of both infection prevention as well as antimicrobial resistance and stewardship, which are now tethered together in the recent CMS CoP ruling on Antimicrobial Stewardship.

Improvement in national CLABSI rates are the result of clinicians and researchers identifying high risk practices and implementing infection prevention bundles to significantly reduce infection risks during central line catheter insertion and maintenance. However, the current focus of surveillance efforts on CLABSI may result in unintended consequences that may not optimize mitigation of Hospital-Onset Bacteremia & Fungemia (HOB) overall. In fact, a narrow focus on CLABSI could result in the placement of a vascular access device which may not be based on the patient's clinical need and risk factors. A broader measure of bacteremia risk to patients, such as the proposed Hospital-Onset Bacteremia & Fungemia Outcome Measure, would realign infection prevention efforts with risks to patient safety. In addition, data shows that much of hospital onset bacteremia may be preventable and widening the scope of reportable infections would enhance patient safety efforts.(1)

In a 2016 article, non-reportable hospital onset bloodstream infections incurred significant increase in mortality and cost of care compared to propensity matched cases.(2) This analysis showed that an automated rubric that minimizes frontline burden, and which is designed to account for contamination and duplicate samples, has equivalent reporting accuracy of HOB as infectious disease specialist case review. We, therefore, believe that the development of an automated, data-driven HOB surveillance measure that keeps patient safety at the center is feasible while optimizing hospital resources.

S. aureus is a common cause of catheter-related bloodstream infections.(3) While the CDC has reported a 73% reduction in S. aureus CLABSI nationally since the central line bundle was initiated, a recent systematic literature review found that 38% of S. aureus catheter-related bloodstream infections were associated with a peripherally inserted intravenous catheter.(3,4) Improved patient outcomes are potentially achievable as S. aureus infections are likely preventable, as a study evaluating the implementation of a peripheral line care bundle demonstrated a 63% reduction in S. aureus infections.(5)

In summary, we believe this measure will enhance infection prevention and antimicrobial stewardship efforts, promote evidence-based practices, and ultimately improve patient care and outcomes. In a risk/benefit schematic, the automation of the definition of HOB as outlined by the MAP draft

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recommendations may help offload frontline data collection time so that infection preventionists can perform rounds in the field and help develop prevention strategies for other sources of hospital onset bacteremia. For most facilities, data requirements of HOB would be less burdensome than the current requirements for CLABSI. While there may be implementation challenges at first—including visibility to the most prevalent sources of bacteremia other than central lines—we believe that an HOB metric will be used to help gage where the high impact sources are, and over time gains can be made in reduction of HOB.

Sincerely,

Kalvin Yu, MD, FIDSA

Vice President, Medical & Scientific Affairs, US Region

BD

References:

(1) Dantes RB, Rock C, Milstone AM, Jacob JT, Chernetsky-Tejedor S, Harris AD, Leekha S. Preventability of hospital onset bacteremia and fungemia: A pilot study of a potential healthcare-associated infection outcome measure. Infect Control Hosp Epidemiol. 2019 Mar;40(3):358-361. doi: 10.1017/ice.2018.339. Epub 2019 Feb 18. PMID: 30773166.

(2) Ridgway, et al. “Performance characteristics and associated outcomes for an automated surveillance tool for bloodstream infection.” American Journal of Infection Control. 2016: Volume 44 , Issue 5 , 567 – 571.

(3) Mermel LA. Short-term peripheral venous catheter related bloodstream infections: a systematic review. Clinical Infectious Diseases. 2017: 65 (10): 1757-62

(4) Centers for Disease and Control. Vital Signs: Central Line-Associated Blood Stream Infections. Morbidity and Mortality Weekly Report. 2011; 60 (No. 9): 233-268

(5) Rhodes, et al. “Reducing Staphylococcus Aureus bloodstream infections associated with peripheral intravenous cannulae: successful implementation of care bundle at a large Australian health service.” The Journal of Hospital Infection. 19(1): 86-91

Intermountain Healthcare

Intermountain Healthcare expresses concern about further action on this measure in light of the significant new burden that would be imposed for hospital infection preventionists at a time when pandemic conditions have already taken a significant toll on this element of the workforce. Intermountain also notes that NHSN's definition of inpatient status is at odds with the definition used by CMS claims and will create significant burden to adhere to specifications as currently proposed.

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Hospital Inpatient Quality Reporting (IQR) Program

MUC2021-136 Screening for Social Drivers of Health

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting (IQR) Program, Merit-based Incentive Payment System (MIPS)

Workgroup
Hospital Workgroup

Measure Description
Percent of beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Numerator
Number of beneficiaries 18 and older screened for food insecurity, housing instability, transportation needs, utility assistance, and interpersonal violence.

Numerator Exceptions
N/A

Denominator
Number of beneficiaries 18 and older in practice (or population).

Denominator Exclusions
N/A

Denominator Exceptions
N/A

State of development
Field Testing

State of Development Details
•Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for HRSN in 21 states, with 33% of beneficiaries screened having at least one HRSN.

-Sources:

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

•CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing

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DOH screening.

-Sources:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Addiction medicine; Allergy/immunology; Behavioral health; Cardiac electrophysiology; Cardiac surgery; Cardiovascular disease (cardiology); Critical care medicine (intensivists); Dermatology; Emergency medicine; Endocrinology; Family practice; Gastroenterology; General practice; General surgery; Geriatric medicine; Gynecological oncology; Hematology/oncology; Hospice and palliative care; Infectious disease; Internal medicine; Interventional pain management; Medical oncology; Nephrology ;Nursing Homes; Obstetrics/gynecology ;Osteopathic manipulative medicine ;Otolaryngology ;Pain management; Palliative care ;Pediatric medicine; Physical medicine and rehabilitation ;Podiatry ;Preventive medicine ;Primary care ;Psychiatry ;Public and/or population health; Pulmonary disease; Pulmonology; Radiation oncology; Rheumatology

Measure Type
Other

Is the measure a composite or component of a composite?
No

If Other, Please Specify
Social and Economic Determinants

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Clinical Data (non-EHR); Standardized Patient Assessments; Patient Reported Data and Surveys

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician; Group; Facility; Other: Beneficiary, Population

In which setting was this measure tested?
Ambulatory/office-based care; Behavioral health clinic or inpatient psychiatric facility; Community hospital; Emergency department; Federally qualified health center (FQHC); Hospital outpatient department (HOD); Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Equity

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
The measure correlate to specific MIPS Quality Improvement Activities as follows:

- Use QDCR data for ongoing practice assessment and improvements (IA_PSPA_7)

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- Use of toolsets or other resources to close healthcare disparities in communities (IA_PM_6)
- Practice Improvements that Engage Community Resources to Support Patient Health (IA_CC_14)
- Provide Clinical-Community Linkages (IA_PM_18)

-Source:
https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2021
The measure correlate to specific MIPS Quality Improvement Activities as follows:
•Use QDCR data for ongoing practice assessment and improvements (IA_PSPA_7)

- Use of toolsets or other resources to close healthcare disparities in communities (IA_PM_6)
- Practice Improvements that Engage Community Resources to Support Patient Health (IA_CC_14)
- Provide Clinical-Community Linkages (IA_PM_18)

-Source:
https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2021

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
In COVID-19's wake, food insecurity, housing instability, IPV, and other basic DOH have reached unprecedented levels – and revealed searing racial disparities. In 2021, 21% of Black individuals are projected to experience food insecurity experience food insecurity, compared to 11% of white individuals. Likewise, 22% of Asian, 22% of Black, and 20% of Latino renters are not caught up on rent, compared to 9% of white renters.

Secretary Becerra has pledged "to take a department-wide approach to the advancement of equity, consistent with President Biden's charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health." In particular, he has noted the

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importance of collecting more robust DOH data to address the disparities exposed by COVID-19 and leveraging the data and experience from the CMMI Accountable Health Community (AHC) model, which has screened nearly one million beneficiaries.

CMS has recognized the importance of making DOH measures standard across programs, identifying the development and implementation of "measures that reflect social and economic determinants" as a key priority and measurement gap to be addressed through Meaningful Measures 2.0.

A growing set of constituencies have called on CMS to provide leadership in measuring and addressing DOH, citing various rationales for doing so. Healthcare experts have increasingly recognized that equity is unachievable without addressing DOH, calling for CMS to require program "participants to uniformly screen for and document drivers of health" and "build DOH measures into MIPS and all APMs." The Health Care Payment Learning & Action Network (LAN) – a group of public and private health care leaders providing thought leadership, strategic direction, and ongoing support to accelerate adoption of APMs – has identified promoting equity and addressing DOH as key facets of APM resiliency.

Likewise, physicians and other providers have called on CMS to create standard patient-level DOH measures – beyond socioeconomic status (SES), hierarchical condition category (HCC) score, or duals status – recognizing that these risk factors transcend specific subpopulations; drive demand for healthcare services; escalate physician burnout; and penalize physicians caring for those patients via worse Merit-based Incentive Payment System (MIPS) scores.

-Sources:

https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf

https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

https://www.healthaffairs.org/do/10.1377/hblog20201216.672904/full/

https://hcp-lan.org/2021-roadshow-deck/

https://physiciansfoundation.org/wp-content/uploads/2020/11/PF-QPP-Open-Comment-Submission-v.f_-.pdf

https://pubmed.ncbi.nlm.nih.gov/27942709/

https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf

https://pubmed.ncbi.nlm.nih.gov/30610144/

https://pubmed.ncbi.nlm.nih.gov/32897345/

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Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Accountable Health Communities Pilot (2017-2022)

What other federal programs are currently using this measure?
Not applicable

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

See attached document "Peer Reviewed Evidence and Relevant Research_MUC2021-136_The Physicians Foundation_5 27 21.pdf" with supporting evidence and research

Evidence that the measure can be operationalized

CMS has the opportunity to leverage and apply CMMI's 5+ years of data and experience with AHC. Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for HRSN in 21 states, with 33% of beneficiaries screened having at least one HRSN. AHC used screening, referral, and navigation data files extracted by NewWave (Centers for Medicare & Medicaid Services [CMS] Enterprise Portal contractor) and generated by Mathematica Policy Research (the AHC implementation contractor) using data submitted by bridge organizations.

-Sources:

https://innovation.cms.gov/innovation-models/ahcm

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

A number of CMMI models and participating entities have incorporated DOH screening and navigation data into their quality frameworks and care management plans for beneficiaries. CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening. CMMI required that by Program Year 3, Track 2 practices would use an electronic screening tool to assess patients' health-related social needs and store an inventory of resources to meet patients' needs; notably, by Program Year 2, Track 1 practices were as likely as Track 2 practices to report implementing these DOH functions, even absent a requirement that they do so.

-Source:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

Likewise, annual evaluations of other current CMMI models, including the State Innovation Model and Next Generation ACOs, report that participants are investing in staffing and infrastructure to conduct DOH screening and navigation. The 2021 Comprehensive End-Stage Renal Disease Care Model evaluation, for example, reported that "[m]any beneficiaries are protein malnourished and don't eat enough fresh produce. Some beneficiaries go to the hospital to get meals." ESRD Seamless Care Organizations have begun to monitor food insecurity and provide food gift cards to both low-income beneficiaries and those above the poverty level, to address beneficiaries' non-adherence to nutritional guidelines and reduce the risk of increased utilization and costs.

-Sources:

https://downloads.cms.gov/files/cmmi/sim-rd2-test-ar3.pdf

https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport

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https://innovation.cms.gov/data-and-reports/2021/cec-annrpt-py4

How is the measure expected to be reported to the program?
eCQM; Claims

Feasibility of Data Elements
Some data elements are in defined fields in electronic sources; Patient/family-reported information: electronic; Patient/family-reported information: paper

Evidence of Performance Gap
CMS has already identified social and economic determinants as both a measurement priority and gap in Meaningful Measures 2.0. Other public and private organizations such as ASPE, NQF and NCQA have identified this as a critical gap.

-Sources:

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress

https://www.qualityforum.org/News_And_Resources/Press_Releases/2019/National_Quality_Forum_Leads_National_Call_to_Address_Social_Determinants_of_Health__through_Quality_and_Payment_Innovation.aspx

https://blog.ncqa.org/ncqa-releases-its-social-determinants-of-health-resource-guide/

Unintended Consequences
A potential unintended consequence of the measure is that health systems and hospitals will not be equipped to act on it due, in part, to the lack of community resources. This challenge was noted as a primary barrier to connecting beneficiaries to resources in the AHC Year 1 evaluation. There is a well-documented and well-tested catalog of additional tools, infrastructure, and investments that can be implemented to support practices in acting on this measure.

-Sources:

https://fhop.ucsf.edu/sites/fhop.ucsf.edu/files/custom_download/Unintended%20consequences%20of%20screening%20for%20social%20determinants.pdf

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

https://nhchc.org/wp-content/uploads/2020/04/NHCHC_Community-Information-Exchange2.pdf

https://governor.nc.gov/news/north-carolina-creates-nation%E2%80%99s-first-statewide-infrastructure-connecting-healthcare-and-human

https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

Outline the clinical guidelines supporting this measure
Not applicable

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Were the guidelines graded?
No

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
Not applicable

Type of Evidence to Support the Measure
U.S. Preventive Services Task Force (USPSTF) Guidelines; Systematic Review; Empirical data

Is the measure risk adjusted, stratified, or both?
Stratified

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Extensive research exists demonstrating increased healthcare expenditures to patients including Medicare beneficiaries associated with DOH. The example below provides the annualized increase in annual healthcare expenditures (PMPY) associated with food insecurity across different disease categories across all payor types in the peer-reviewed literature:

•Diabetes Mellitus: $4,413.61

•Hypertension: $2,175.20

•Heart Disease: $5,144.05

•Overall: $1,863

-Source:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

The AHC Year 1 evaluation found that Medicare FFS beneficiaries in the Assistance Track intervention group had 9% fewer ED visits than those in the control group in the first year after screening. (No Medicaid utilization/cost data reported yet.)

-Source:

https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

Cost Avoided Annually by Medicare/Provider
Unable to determine – though the cost avoided annually is likely to be significant given the research demonstrating increased utilization, readmissions, cost and increased financial liability for providers

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caring for patients with increased social risk.

Source of Estimate
Sources:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

Also see attached review of the research literature for additional cost studies related to DOH.

Year of Cost Literature Cited
Estimated expenditures in 2015 dollars

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Surveys

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Not applicable

Total Number of Patients and/or Caregivers Consulted
3162

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
Not applicable

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2441

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
0

If yes, what is the frequency of requests for survey data per year?
1

If yes, are the survey data to be collected during or outside of a visit?
Prior to visit; During visit; After visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys; Focus groups; Standard TEP

Total Number of Clinicians/Providers Consulted
10078

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Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
8800

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
3224

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
3

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
These results are the first to suggest that both the AHC and YCLS have high reliability and concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informed care.
-Source:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/#ref38

Type of Reliability Testing
Measure Score Reliability; Data Element Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
1008

Reliability Testing Statistical Result
Within social domains, percentages reporting asocial risk tended to be higher by the AHC than the YCLS. Using unadjusted kappas, the AHC and YCLS items had substantial agreement for measures of food insecurity only. When examining the adjusted kappas that account for bias and prevalence, agreement between the AHC and YCLS items was substantial or higher (kappas > 0.60) for all social risks except housing quality (kappa = 0.52). The YCLS and CHW had substantial agreement (kappa 0.75) on housing.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

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If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Internal Consistency; Predictive Validity; Other: Empirical validity (through AHC and CPC+ practice implementation across 3+ million beneficiaries over last ~ 5-year time frame) and Psychometric and Pragmatic Property Analysis (see https://pubmed.ncbi.nlm.n)

Validity Testing Sample Size
Study 1: 1,008 ; Study 2: 30,098 ; Study 3: 60,000

Validity Testing Statistical Result
•Study 1: A reported social risk on the AHC and YCLS measures was strongly associated with having fair or poor self-rated health

-Source:

https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

Study 2: HFSS questions 1 and 2 were most frequently endorsed among food-insecure families (92.5% and 81.9%, respectively). An affirmative response to either question 1 or 2 had a sensitivity of 97% and specificity of 83% and was associated with increased risk of reported poor/fair child health (adjusted odds ratio [aOR]: 1.56; P < .001), hospitalizations in their lifetime (aOR: 1.17; P < .001), and developmental risk (aOR: 1.60; P < .001).

-Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: Sensitivity of each two-item combination was high for the US population and high-risk demographic groups compared with the eighteen-item CFSM (Table 2). Sensitivity ranged from 96·4 % for items 2 and 3 for households with children and incomes <200 % of the federal poverty line, to 99·8 % for items 1 and 3 for Spanish-speaking households. (results for all combinations are available from the corresponding author upon request). Specificity was lower, ranging from 73·7 % for items 1 and 2 for households with children and incomes <100 % of the federal poverty line, to 94·5 % for items 2 and 3 for households with a respondent aged >60 years. Accuracy was high for all two-item combinations.

-Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Validity Testing Interpretation of Results
Study 1: These results are the first to suggest that both the AHC and YCLS have concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informed care.

-Source:

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https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

Study 2: A 2-item FI screen was sensitive, specific, and valid among low-income families with young children. The FI screen rapidly identifies households at risk for FI, enabling providers to target services that ameliorate the health and developmental consequences associated with FI.

-Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: The test characteristics of multiple two-item combinations of questions assessing food insecurity had adequate sensitivity (>97 %) and specificity (>70 %) for widespread adoption as clinical screening measures.

-Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
33%

Benchmark, if applicable
Not applicable

Measure Contact Information

Measure Steward
Other

Measure Steward Contact Information
Robert Seligson
4033 Lila Blue Lane
Raleigh, NC 27612
bob@physiciansfoundation.org
919-306-0056

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

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Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-136 Screening for Social Drivers of Health

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes
Justification and Notes: This measure assesses the percentage of patients screened for health-related social needs and is consistent with the Meaningful Measures 2.0 priority to develop and implement measures that reflect social and economic determinants. There are no similar measures in the Hospital IQR Program.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes: Health outcomes are ~80 percent driven by socioeconomic factors, health behaviors, and the physical environment (Hood et al, 2017). Reviews have collected numerous studies identifying a causal relationship between poor health outcomes and homelessness (Stafford and Wood, 2017), food insecurity (Staren, 2020), and other needs screened for by the tool cited in this measure (Davidson et al, 2020). The process of screening itself is consistent with guidelines promulgated by the American Academy of Pediatrics, The American Academy of Family Practitioners, and a recommendation by the U.S. Preventive Services Task Force. An evaluation of a program offering program navigation services to patients screened using this tool found a statistically significant decrease in ED visits, one example of interventions predicated on the screening to improving health outcomes.

Does the measure address a quality challenge?
Yes/No: Yes
Justification and Notes: The measure is conceptually related to a critical quality challenge. The developer notes that identifying and addressing social determinants of health has become a top nationwide priority for leaders in healthcare. According to Fraze et al (2019), just 16 percent of physician practices screened patients for all five social needs identified in this measure, and 33 percent of practices did not screen patients for any needs. In the 2017-2020 years of evaluation of a CMS program based on the measure's screening tool, 34 percent of beneficiaries screen were positive for at least one need, indicating a substantial unmet need for screening and a performance gap in the measure result.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes
Justification and Notes: There are no similar measures in the Hospital IQR program or other federal quality programs.

Can the measure be feasibly reported?
Yes/No: Yes

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Justification and Notes: To report the measure, providers must collect the total number of patients and the number of patients who were screened for all five elements; the only demographic information needed is patient age. The screening tool data can be electronically collected and recorded; therefore all of these data points should be available to providers for reporting. The screening tool has been in use in 21 states across the US, with nearly one million patients screened. MAP acknowledged that the measure specifications are not specific to a particular tool.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is specified and has been trialed in Hospital inpatient acute care facilities. The MAP acknowledged that although the reliability and validity has been examined for the screening tool, no such testing has been evaluated by the NQF endorsement committees. The MAP Hospital workgroup noted that the measure denominator should be expanded beyond Medicare beneficiaries.

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?

Yes/No: Yes

Justification and Notes: The developer notes one unintended consequence is that health systems and hospitals may not be equipped to act on identified needs. This may lead to frustration for both patients and providers as well as ethical challenges if these needs remain unmet even after referrals (Garg et al., 2016).

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- It is great to know this information, but if you're calling attention to issues that clinicians cannot support or to which they can intervene, this is a concern
- Hospitals are more equipped to steering patients to community resources and having social/community workers onsite to facilitate discharge to the community

Data collection issues:

- There was a question on how this measure data will be collected
- However, the Advisory Group agreed that it is important to start the standard collection of this information. The developer commented that by introducing this measure into CMS programs, it will help drive standardization

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- Concern with the amount of information that is needed for collection and being burdensome for admission or discharge settings
- The measure would be standard, but the mechanism by which the information would be collected would be left up to the providers.

Calculation issues:

- The scientific acceptability of this measure is a concern and the need for NQF endorsement

Unintended consequences:

- Concerns that health systems and hospitals collecting this information have not connected with community resources, so they are not prepared to act on the needs identified from patients

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.5
1 – 1 votes
2 – 3 votes
3 – 1 votes
4 – 6 votes
5 – 3 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- Aligned with the vision of CMS to improve health equity

Data collection issues:

- Concern regarding the standardization to put in place such that the screening is uniform across the country. The developer clarified that the measure is the standard and the interventional tools would tie to the measure. The data collected would be standardized, but the process for collection will be left up to the provider.
- It is important to begin to collect these data, as this will further help to gain more resources for these facilities that are serving a high number of patients with social needs.
- There may be some issues with people being labeled and not answering the questions truthfully. Also not everyone has a trusted relationship with a provider (or even a PCP) and the hospital may be the best way to capture these data for some individuals. Hospitals are more likely to have resources and, therefore, important to include.
- Some concern regarding the intensity of the resources that are required to screen. Implementing a measure across various IT systems can be challenging for some providers including critical access facilities. Many facilities also will have a lack of community resources and the link to those may also be non-existent.

Calculation issues:

- Stratification should consider the disabled community and getting access and resources
- There was some discussion on how this measure was validated and the developer mentioned that this measure has been validated through the ACH pilot

Unintended consequences:

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- Concern about what providers should do with patients that screen positive. There was discussion that you need to collect the data in order to implement change. Some Advisory Group members agreed that the consequences of not asking are greater than asking.
- However there is an expectation that is set up when these questions are asked, and if there are processes in place there would be frustration felt by providers and patients. Identification without resources is not helpful. There needs to be a standardized approach.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 4.1
1 – 0 votes
2 – 2 votes
3 – 3 votes
4 – 9 votes
5 – 10 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This measure assesses the rate at which providers screen their adult patients for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety. As the first screening measure addressing social determinants of health and health care equity, this measure is consistent with CMS' Meaningful Measures 2.0 priority areas.

Summary: What is the potential impact of this measure on quality of care for patients?
This measure addresses a significant performance gap, where despite the fact that approximately one-third of patients would screen positive for one or more social needs, 84% of physician offices do not screen for all five needs. This measure is consistent with recent guidelines from the American Academy of Family Practitioners, the American Academy of Pediatrics, and the U.S. Preventive Services Task Force, which are inspired by research finding that health outcomes are largely driven by social determinants of health. Screening for health needs can help connect patients to social services to ameliorate those needs.

Conditional Support for Rulemaking pending NQF endorsement

Section 3: Public Comments

Sacramento Native American Health Clinic
FQHC patients are generally lower on the socioeconomic and political ladder. Health outcomes DO NOT need to reflect that, yet they do. Many providers do not ask about these HRSN of patients and potentially miss important opportunities to intervene. If we collect this data, we can ask for more help

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and create a better case for policy changes. The additional time added to assess social needs would be offset by implementing interventions that bend towards equity.

Indiana University Health
Yes, we know 80% of patients health conditions can be improved if we assist with social need gaps, rather than focusing on the health issue alone. This is really important to move forward with screening and assisting those patients further who screen positive.

Koss on Care LLC
Initial screen is important particularly to set baseline metrics, but screening without any follow on intervention will not advance improvements for patients and families. Screening needs to have accompanying socio-demographic metrics to also track and address disparities and inequities. Without an understanding of the level of screening for these known social determinants we cannot start to address major drivers of health and health outcomes. As EHR increasingly facilitate & capture screen it should be reasonably cost effective. Improved sharing of such data across providers could also reduce the burden.

University of Texas at Austin
It is incredibly important for hospital settings to screen for social determinants of health (SDH), particularly amongst Medicare patients. While the benefits outweigh the burden of data collection, hospitals will need to have the appropriate staff for assessing and addressing SDH, such as social workers and community health workers. Ideally, the social workers would be based in the hospital while community health workers would be engaged in transitional care post discharge. This will increase buy-in among hospital staff and ensure that there are appropriate responses to patient needs.

Next Wave
This is an important first step in making Quality Measures in use truly patient-centric, by incorporating the patient's social needs as well as their clinical needs into care provided ("I am NOT just my condition"). Because these needs differ significantly by age, they should be reported by age/category (at minimum Over/Under 65). Because this is the first use of Social Driver metrics, it provides an opportunity to learn and refine over time. Effort should be taken to capture some details beyond the bare minimum public reporting ratio to allow further research and refinement for the future, for example: Separate numerator and denominator, Medical vs. Surgical care. This could be accomplished by adding Z-codes to the claims data.

BHE Group
This measures is needed to initiate focus on SDOH at an entry level. However, it does not address the goal of integrating the screening result into the care plan, executing on it and measuring the clinical impact of having it (or not having it) addressed. At minimum, a 2nd measure should also include % of results obtained through screening incorporated into the patient's care plan.

NewWave
Both MUC2021-136 (Driver of Health Screening Rate) and MUC2021-134 (Driver of Health Screen Positive Rate) are important baby-steps to begin measuring drivers. They are simple process measures that may be valuable in starting the measures we really need to be working toward. Knowing the rate of Screening and of those screened which had positive indicators of food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety will do little to improve the rate at which we implement programs that have a meaningful\measurable impact on effecting this QOL deteriorating drivers that rob value from any health care delivery received by effected individuals.

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It is critical that these "conversation starter measures" are not considered an end in themselves but are in fact simple measures that we can do today with little controversy or change in the as is state of the care delivery system. Until we begin to measure the closed loop referral process and gather population level impacts and gaps the value of measures of drivers will be little more than the minimum we must be doing to get started on the more important work to be done to address the blockers to better inter-sector and interoperable whole-person care that is called for by everyone.

Blue Shield of California Foundation

The COVID-19 pandemic has exposed long-standing racial and economic injustices embedded in our health care system. This has led to a renewed commitment to improve health equity and address the drivers of health (DoH) that account for 80 percent of health outcomes and have a disproportionate impact on communities of color. These include stable, affordable housing; healthy food; reliable income; and interpersonal safety, among others.

Advancing health equity and addressing DoH will require changing how and what we measure in health care. Measurement matters because it equips providers with data to identify and address unmet needs and allows policymakers and payers to account for DoH in payment models.

We thus strongly encourage the Measure Applications Partnership to support for rulemaking both MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021-136 (Screening for Social Drivers of Health). Despite the well-documented impact of DoH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DoH measures in any Centers for Medicare &Medicaid Services' (CMS) programs. Even without such measures, the impact of DoH interventions are much-referenced in the health care discourse and literature, but remain functionally invisible in federal health care policymaking.

For example, a growing number of CMS Innovation Center models – Accountable Health Communities (AHC); Comprehensive Primary Care Plus; Maryland Total Cost of Care; State Innovation Models Round 2; and more – have screened millions of Medicare and Medicaid beneficiaries for DoH in thousands of inpatient and outpatient clinical settings across the country, but largely without the benefit of standard DoH screening tools or measures from CMS. As a result, CMS cannot systematically compare or use the data.

Recognizing the absence of DoH and race and ethnicity data as an issue, incoming CMS leadership in August 2021 cited the need for "patient-level demographic data and standardized social needs data" as a key element in its commitment to embedding equity in all models and demonstrations. The recently released CMS Innovation Center strategy report took this a step further by saying all new models will require participants to collect and report beneficiaries' demographic data and social needs data, when appropriate. Providers have joined the call for standardized, patient-level data collection for DoH, citing the impact of these drivers on patients, health care costs, and physician burnout. These proposed DoH measures have been used in more than 600 clinical practices through the AHC model and have been subject to rigorous and independent validation. The AHC model found that 74% of navigation-eligible Medicare and Medicaid beneficiaries who were screened using these DoH measures opted in for navigation, nearly twice the projected estimate of 40%. Likewise, a large study in 2020 by Kaiser Permanente found that 85% of patients were in favor of health systems asking patients about social needs, and 88% were in favor of health systems helping to address those needs. The introduction of the first DoH measures into core federal payment programs would be significant in its own right – making

visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all.

If approved, these DoH measures can be improved over time through CMS's annual measure review process and can provide the groundwork for comparable measures for the Medicaid and CHIP Child and Adult Core Sets and guidance for states in their efforts to standardize DoH data. Further, these initial DoH measures could lay the foundation for subsequent measures focused on ensuring patients secure the resources they need to be healthy and accelerating/enabling investments in community capacity. In particular, these DoH measures will provide crucial data on the prevalence of unmet social needs among beneficiaries and other learning to enable more effective public and private sector investments in the technical/IT infrastructure, community-based navigation workforce, and capacity building and sustainable sources of funding necessary to enable the equitable integration of healthcare and community social services.

Citations: https://blueshieldcafoundation.org/newsroom/press-releases/20210323/survey-documents-uneven-impact-covid-19-californias-communities
https://www.commonwealthfund.org/sites/default/files/2019-07/COMBINED_ROI_EVIDENCE_REVIEW_7.15.19.pdf
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Institute for Healthcare Improvement (IHI)
Public Statement on 2021 CMS Measures Under Consideration:

Drivers of Health December 8, 2021

Today we know that social factors influence health outcomes. We also know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health (DOH). In COVID-19's wake, food insecurity, housing instability, interpersonal violence, and other DOH have reached unprecedented levels and revealed massive racial inequities. In 2021, 21% of Black individuals are projected to experience food insecurity, compared to 11% of white individuals. Likewise, 20% of Asian, 28% of Black, and 18% of Latino renters are not caught up on rent, compared to 12% of white renters (references below.)
The challenge now is to figure out how to work on these drivers of health in a fundamentally different way. In this context, it is untenable for the health care system to continue to address DOH primarily through special pilots or initiatives, as the National Academies of Sciences, Engineering, and Medicine (NASEM) demonstrated in their report, "Integrating Social Care into the Delivery of Health Care: Moving Upstream to Improve the Nation's Health."

Consistent with recommendations in the NASEM report, we are pleased that CMS has included two beneficiary-level DOH measures (MUC2021-134: Screen Positive Rate for Social Drivers of Health and

MUC2021-136: Screening for Social Drivers of Health) on the Measures Under Consideration list in the equity domain. These measures should be recommended by the Measure Applications Partnership (MAP) in this review cycle, as a reflection of HHS' and CMS' commitment to equity and addressing the health-related social needs of the millions of beneficiaries they serve.

These measures, stratified by race/ethnicity, are (1) crucial to identify racial disparities in DOH, including those driving health inequities; (2) will lay the foundation for health care institutions to help guide beneficiaries to the resources they need to be healthy; and (3) will lead to more accurate risk adjust payment models. Drivers of health screening are also crucial in creating the imperative for public and private investments in the workforce and technology needed to reliably connect beneficiaries to the resources they need. And, most importantly, these measures can help ensure those resources exist in the first place, through cross-sector and community-based partnerships.

In 1999, the Institute of Medicine published To Err is Human in part to "…reveal the often startling statistics of medical error." That report did not promise easy solutions, but it asserted that it was time to "…break the silence that has surrounded medical errors and their consequence." Similarly, it is time to make visible the reach and impact of DOH by enacting the first-ever DOH measures in federal payment programs.
Citations:
https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf
https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-economys-effects-on-food-housing-and https://nam.edu/wp-content/uploads/2021/09/An-Equity-Agenda-for-the-Field-of-Health-Care-Quality-Improvement.pdf https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556
https://www.nap.edu/cart/download.cgi?record_id=25467 https://www.medicaid.gov/federal-policy-guidance/downloads/sho21001.pdf
https://www.healthaffairs.org/do/10.1377/hblog20210414.379479/full/

Legacy Community Health

For the first time, CMS is considering two quality measures related to social risk screening as part of this year's 44 new Measures Under Consideration (MUCs) list. The two measures are: Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136) Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134).

We have been screening for these measures for years and have found them to be a key driver in health outcomes. It would be helpful to have a standardized approach so that we can further our efforts of proving that social determinants of health are just as important to overall health as traditional healthcare.

Duke Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy encourages the inclusion of measures addressing social drivers of health (SDoH) in CMS quality reporting programs. The impact of these drivers on health is well documented, and a growing number of efforts are under way to examine how health care providers and organizations can better identify and address individuals' SDoH-related needs. Among these efforts are those examining how to leverage value-based payment (VBP) models to better address SDoH.1 Our work has found VBP models have the potential to support the infrastructure and cross-sector

relationships needed to identify and comprehensively address SDoH-related needs.2 However, the current dearth of SDoH-related quality measures makes it difficult to embed accountability for addressing SDoH into VBP models. Development and implementation of SDoH-related quality measures are needed if VBP efforts to meaningfully address SDoH are to be successful.

The addition of the MUC2021-136 and MUC2021-134 measures to the Hospital Inpatient Quality Reporting Program and Merit-based Incentive Payment System would reflect the emphasis needed on advancing SDoH-related quality measures, especially if they can be clearly linked to a strategy for supporting improvement in the SDOH risk factors reflected in such measures. Such a strategy should include more systematic collection and reporting of SDoH-related data, development of the infrastructure needed to support partnerships across sectors (e.g., health care, education, justice), and implementation of payment models that can support and sustain the delivery of SDoH-related services. The inclusion of SDOH-related quality measures in CMS quality reporting programs is one way to support progress in implementing such a strategy.

References:
1.Sandhu S, Saunders RS, McClellan MB, Wong, CA. (2020). Health Equity Should Be A Key Value in Value-Based Payment and Delivery Reform. Health Affairs Blog. Accessed December 3, 2021. http://www.healthaffairs.org/do/10.1377/hblog20201119.836369/full/
2.Crook HL, Zheng J, Bleser WK, Whitaker RG, Masand J, Saunders RS. (2021) How Are Payment Reforms Addressing Social Determinants of Health? Policy Implications and Next Steps. Accessed December 3, 2021. https://www.milbank.org/publications/how-are-payment-reforms-addressing-social-determinants-of-health-policy-implications-and-next-steps/

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Hospital Inpatient Quality Reporting (IQR) Program for several reasons.

While the FAH supports the overall intent of this measure and MUC2021-134, Screen Positive Rate for Social Drivers of Health, we were unable to determine why the specific social drivers of health were selected, the degree to which they are aligned with the work of the Health Level 7 Gravity Project or the United States Core Data for Interoperability (USCDI), and whether the intended patient population is Medicare beneficiaries or those aged 18 years and older since the wording is not clear. In addition, the developer did not provide any evidence demonstrating that this process is linked to improvements in health outcomes nor has testing of the measure been completed.

Furthermore, the FAH requests that the Hospital Workgroup consider the degree to which this measure could be considered actionable. This measure assesses the rate of screens completed by a hospital in the absence of any information on the degree to which a facility has been equipped with the necessary resources and tools to address the individual's needs. Any implementation of this measure is premature until these resources and tools are widely available.

The FAH believes that these questions and concerns must be addressed and endorsement by the National Quality Forum should be achieved prior to implementation of this measure in the Hospital IQR Program. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not

Support with Potential for Mitigation."

American Medical Association

While the American Medical Association (AMA) supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we do not believe that the implementation of this process measure, in the absence of any resources or tools that would be widely and readily available to hospitals, should be pursued at this time. Measures must be actionable and facilitate improvements in patient care. While all hospitals can identify and facilitate addressing social needs, they cannot and should not be held responsible for resolving them. Other strategies such as stratification of populations by race, ethnicity, and social drivers of health should be employed.

In addition, the developer did not provide any evidence to demonstrate that the collection of these data alone will drive improvements in health outcomes nor is it is clear why the developer selected the specific social drivers of health for this measure and MUC2021-134: Screen Positive Rate for Social Drivers of Health. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). We were also unable to determine which patients the measure intended to capture since the word "beneficiaries" is typically used when a measure applies to those individual with Medicare Fee-for-Service, yet the denominator language also indicates that it would be any person 18 years and older. In addition, the measure itself is not yet tested. We believe that many of these discrepancies would be resolved if the measure was fully specified and demonstrated to be evidence-based, reliable, and valid.

Because we do not believe that this measure will result in effective change, we request that the highest level of MAP recommendation be "Do Not Support."

IU Health

We would like to ensure that multiple evidence-based screening tools can be used including PRAPARE. Since we do not use the AHC screening tool but PRAPARE instead, we want to ensure that this would be an acceptable format.

The Coalition to Transform Advanced Care

We support this measure and very much appreciate its addition to the MUC list. We believe this will begin to gather this important information in a more systematic way and help to help build better links to community services that address these needs.

Because this is a new area for measurement, we are not yet sure what application it will have but believe it will certainly inform QI efforts and could also be used for payment in value-based arrangements.

We see little implementation issues in gathering the information, which is what the measure requires, but hope that it will be the beginning of a more comprehensive way not only to screen for social drivers of health but to refer and then deliver any needed services. However, this is an important first step

findhelp

MUC2021-134 (Driver of Health Screen Positive Rate) MUC2021-136 (Driver of Health Screening Rate) Re: Comments for NQF public comment period on CMS MUCs

In response to the National Quality Forum (NQF) public comment period on Centers for Medicare & Medicaid Services' (CMS) measures under consideration (MUCs), please see below comments related to

MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation.

About findhelp

Founded in 2010, findhelp, a Public Benefit Corporation runs the largest social care network in the United States and has served more than eight million Americans. Our mission is to connect all people in need with the programs that serve them with dignity and ease. As part of fulfilling this mission, we will always maintain findhelp.org, a free and anonymous search tool for identifying free and reduced cost programs in every U.S. zip code. Our network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as tens of thousands of Community Based Organizations (CBOs). Findhelp's interoperable social care technology works with electronic health records (EHRs) and other platforms to help clinicians and other partners address the social needs of individuals in a seamless fashion.

Comments

Findhelp appreciates the opportunity to share feedback with NQF related to proposed quality measures specific to Social Drivers of Health (SDoH).

1. This measure recognizes social needs screening as an important clinical tool.

Recognizing the value of Social Drivers of Health (SDoH)

Screening for SDoH provides clinicians with actionable data on health-related social needs that may be impacting the whole person of their patients. Capturing SDoH risks and screening information can better inform provider organizations about the needs of their patients and communities. This information can help healthcare organizations connect patients to needed resources, prioritize partnerships with CBOs and vendors, and inform capacity planning.

For example, findhelp customer Boston Medical Center (BMC) developed the THRIVE SDoH Screening and Referral program to identify and address detrimental social factors preventing patients from thriving, such as unstable housing, food insecurity, financial instability, and other issues. Through the THRIVE screener, patients identify their social needs, and BMC staff refer them to both resources at BMC and in the community using the THRIVE Directory (powered by findhelp).

Governments at all levels make significant resources available to consumers related to their social needs. Such resources could include, but are not limited to, those used to address food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Yet, a clinician's ability to support a patient is only as strong as his or her awareness of the patient's needs. Screening for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety gives providers the opportunity to impact a patient's health in ways far beyond clinical interventions.

Unfortunately, connecting those resources to consumers who need them – including the nation's Medicare and Medicaid beneficiaries – can be challenging. We encourage CMS to make identifying social care needs and connecting these consumers to available resources a core part of their healthcare quality

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and health equity strategies moving ahead.

Incentivizing measurement of SDoH

In particular, we encourage CMS to adopt MUC2021-134 and MUC2021-136 into federal payment programs. These will be the first standard SDoH measures included in federal payment programs and will provide a starting point to incentivize healthcare providers to measure and report on patients' SDoH needs.

2. The benefits of the measure outweigh the burden of data collection and reporting.

Data collection is both valuable and feasible

We believe that not screening for SDoH represents a larger burden to providers than conducting the screenings. Not building SDoH measures into the health system increases the burden on physicians as SDoH are still part of their patients' clinical reality. As healthcare providers increasingly recognize the impact of SDoH on their patients and practices, especially in light of COVID, they have called for CMS to measure what matters.

While this screening work is happening around the country already, there is a strong need for a national standard for this process. In the absence of CMS SDoH measures, physician organizations (e.g., findhelp customers American Academy of Family Physicians and American Academy of Pediatrics) have developed ad hoc SDoH screening guidelines. More than 100 findhelp customers currently using our platform to screen patients for SDoH needs, and many more screen directly in their EHRs and care platforms.

CMS has already implemented these measures in a limited fashion, providing NQF and other stakeholders an opportunity to review the tangible impact to clinicians of undertaking the screening. The measure developer (the Physicians Foundation) submitted these SDoH measures because they are currently in use in the CMS Innovation Center's Accountable Health Communities model, where they have been effectively tested and implemented over 5 years with nearly a million CMS beneficiaries in 600 clinical sites and multiple practice settings across the country.

Interoperability of social care networks

After screening patients for SDoH needs, many healthcare provider organizations will want to facilitate the connection of their patients with needed services. To facilitate this vital next step, the technology exists to integrate social care referrals into EHRs or other platforms. Through platforms such as findhelp, healthcare systems, providers and CBOs are able to receive and exchange social care data from various sources within their own environment and systems of record.

January 13, 2022
MUC2021-134 (Driver of Health Screen Positive Rate)
MUC2021-136 (Driver of Health Screening Rate)
Re: Comments for NQF public comment period on CMS MUCs
In response to the National Quality Forum (NQF) public comment period on draft recommendations offered by the Measure Application Partnership (MAP) workgroups that

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convened last month, please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation. These comments were shared with the MAP prior to last month's meeting.

The MAP's initial recommendations related to MUC2021-134 and MUC2021-136 are a welcome development. Findhelp encourages the MAP to continue its support for the measures in the final recommendations to HHS.

Kaiser Permanente

KP supports development and adoption of reliable, evidence-based, well-tested measures of social drivers of health. KP currently measures social drivers with a standard instrument for quality and performance improvement, and we have set aggressive targets to rapidly expand standard screening across the enterprise. Our unique experience with implementation of these measures at significant scale with our 12.5 million members enables us to contribute to the evidence base for these measures, including impact on health, care, cost, and equity, and we will continue to do so through our robust social health research and evaluation efforts over the next few years. We recognize these upstream measures are new in the measure development and review process and may present special challenges. We offer our support and collaboration, and request to stay informed and connected throughout the process.

Children's HealthWatch, Boston Medical Center

Measure Applications Partnership (MAP)
Currently selected 2021 MAP Measures Under Consideration (MUC)
Comments submitted

On behalf of Children's HealthWatch, we applaud the National Quality Forum (NQF) Measures Application Partnership's consideration of MUC 2021-136 (Driver of Health Screening Rate) and MUC 2021-134 (Driver of Health Screen Positive Rate). Children's HealthWatch seeks to improve the health and development of young children and their families by informing equitable policies that address and alleviate economic hardships and by dismantling systems of institutionalized discrimination and inequity at the root of these hardships. Our work begins with research through interviewing caregivers of young children on the frontlines of pediatric care, in urban emergency departments and primary care clinics in five cities: Boston, Minneapolis, Little Rock, Baltimore, and Philadelphia. Since 1998, we have interviewed over 75,000 caregivers of children under four years of age and analyzed the data to determine the impact of social risk factors (individual-level adverse social determinants of health) and public policies designed to address those social risk factors on the health and development of young children and the well-being of their families. Specifically, our research focuses on the following: nutrition, housing, health care, child care, utilities, income and wealth, employment, Adverse Childhood Experiences and Experiences of Discrimination. Our research – in addition to that of others – shows that lack of access to basic needs is associated with poor child health and development, poor parental physical and mental health, higher child hospitalization rates, and learning and behavioral/emotional impairments. Health consequences are often compounded, as they are frequently experienced simultaneously, often as a result of limited income and resources.

How would adding this measure add value? How would the measure improve patient outcomes?

Based on decades of our research, and the research of others, we stress the importance and value of

measuring of social risk factors to identify and address unmet social needs (social needs differ from social risks insofar as they convey the patient's preferences and priorities regarding the social risk) and enable policymakers and agencies such as CMS and other payers to incorporate them in value-based payment models. The measures under consideration (MUC 2021-136, MUC 2021-134) also offer a valuable opportunity to provide a foundation for comparable measures for the Medicaid Adult and Child Core Measure Set and guidance for states in their efforts to standardize these data.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of measuring social risk factors far outweigh the burden of data collection and reporting. Numerous studies have shown relatively high acceptability of social needs screening and referral among both patients and providers (https://bit.ly/3rSik2v, https://bit.ly/3rOPlN5). Initial evaluation of the Accountable Health Communities (AHC) Model found that among navigation-eligible beneficiaries who reported unmet social needs, 41% had one unmet social need and nearly 60% reported having multiple unmet social needs. While research and implementation of social needs screening and intervention has grown substantially over the past decade, providers and health systems struggle with heterogeneous screening tools and interventions. This contributes to absence of consideration of unmet social needs in federal health care policymaking. The prospect of these two measures being utilized in Medicare public reporting and performance-based payment programs would be beneficial because they would both elevate the importance of these issues for health at the federal level and shed much needed light on social risk factors in a standardized way that allows for accurate comparison of data across settings and communities. Furthermore, if these measures are stratified by race and ethnicity and by age, policymakers and agencies will be prepared to effectively target resources and actions that advance health equity and address long-standing disparities in health outcomes.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

These measures (MUC 2021-136, MUC 2021-134) offer opportunities to be used for QI, maintenance of certification, payment, and public reporting.

We consider MUC 2021-134 to be an indicator of the identified risk of the population. Thus, the measure and specific screening tools included in the AHC questionnaire it relies on are not capable of disease surveillance or diagnosis of certain social risk factors precisely because the AHC questionnaire was designed as a screening tool and identifying social risk factors in clinical settings for diagnosis and intervention may require further assessment. . In fact, our research has identified significant discordance among the AHC questionnaire housing questions and Children's HealthWatch housing questions. The two tools captured different housing-related risks and contributed to different health consequences, which were relevant to different subpopulations. These findings demonstrate that the choice of question is important to identifying the specific risk. We raise this point to underscore that any screening tool will inherently have limitations and thus further discussion with health providers and thoughtful linkages to interventions are critically important next steps. Thus, the AHC questionnaire does not measure all possible forms of social risk but instead is designed to capture specific domains currently identified as prevalent risk factors in health care and public health literature. Given the fact that there never will be nor could there be a single social risk screening tool that identifies every health-related social need for every person, the evidence-based approach taken to develop the AHC tool along with its wide adoption over the past few years, indicates that it is the best option available for the

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purposes of accomplishing the goals of these measures.

We suggest creating a paired measure of improvement over time in the specific social risk factors dimensions as a better measure than simply a one-time measure of proportion, again stratified by race and ethnicity and age. This improvement measure is similar to what the NQF Measure Incubator project has developed for the forthcoming food insecurity measures (https://bit.ly/3pGLZt0). Further, also aligned with the NQF Measure Incubator project's forthcoming food insecurity measures, we suggest a paired measure on appropriate interventions that have occurred as a result of identification of unmet social needs on screening. Interventions need flexibility to adapt to local context, resources, and community needs, however, certain core principles and best practices can still be standardized. Without an intervention-focused measure, we miss opportunities to understand the landscape of programs and interventions that serve the needs of families, and coordinate strategies that target or improve interventions.

Any model of care that seeks to measure outcomes should focus measurement and evaluation on providers' and institutions' ability to effectively 1) measure and 2) address health related social risks or concern (e.g., food insecurity, housing instability, transportation). A recent report from the National Committee for Quality Assurance (NCQA) describe health care organizations' use of both process (i.e., the number of patients screened or referred) and outcome (i.e., improvement from a baseline, meeting quality targets, impact on health care utilization) measures to evaluate the impact of their overall strategy and specific interventions. This report also made note that the field currently focuses more on process measures for specific social needs rather than health outcomes and health care utilization outcomes. A broad set of outcome measures beyond process measures is an area for further exploration.

Are there implementation challenges?

Challenges do exist, including limited provider time to screen and intervene, lack of a multi-domain screening tool that encompasses any and all social risk factors individuals may experience, and ability of institutions to suitably identify needs and provide targeted resources. The CMS Innovation Center and its 5-year AHC Model, while still under way, is an encouraging approach that demonstrates the need and political will to address this critical gap. Beyond expansion of this model, the Improving Social Determinants of Health Act of 2021 is a promising legislative opportunity to address limited health care resources and challenges to implementation of effective value-based care. Supported by hundreds of professional health organizations and networks, health insurers, and community-based organizations, the Improving SDOH Act would enable health providers and systems to better coordinate, support, and align SDOH best practices and capacity building activities. In coordination with the Centers for Disease Control and Prevention, federal agencies such as CMS, and local public health departments, the Act would support these activities by ensuring that there are resources and policies in place to intervene effectively on unmet needs and their health correlates. Specifically, through increased funding opportunities, technical training, and evaluation assistance, scaled data collection and analysis, and identification and coordination of best practices, this act would increase the public health sector's capacity to engage with the health care sector and fully address SDOH priorities beyond temporary referrals and interventions. Efforts like these are important to ensure that health systems are not only supporting their patients in achieving holistic health, but that providers also have the systems and resources to do so in ways that are sustainable, evidence-based, and avoid harms to patients.

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Do you recommend this measure?

Yes

ZERO-The End of Prostate Cancer

On behalf of the all those managing prostate cancer and navigating prostate cancer care (now and in the future), ZERO - The End of Prostate Cancer submits these comments in support of identifying those who screen positive for specific social needs such as food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety in the Hospital IQR and the MIPS program. Research has shown that socioeconomic factors are a substantial driver in the racial/ethnic differences in prostate cancer across the cancer continuum from prevention to end-of-life care. Families managing a prostate cancer diagnosis and navigating prostate cancer care engage with several staff, providers, and administrators in the healthcare delivery system; and this process often proves to be very complex, and to be substantially influenced by the socioeconomic resources of the patient and on how well the care delivery system has integrated “social care” into medical care. Not surprisingly, generally racial/ethnic minority and low socioeconomic status patients have worse health outcomes as they navigate the healthcare/cancer care delivery system. To address this issue, there have been several recent efforts to facilitate the integration of screening and addressing patient social needs in health care delivery; yet, there is no agreed upon standard tool for screening patients. Thus, it is critical that CMS facilitates the integration of standard measures and creates a pathway for identifying those with the social needs proposed in this new measure; and create financial incentives and risk models/frameworks that recognize the social factors that contribute to worse health outcomes and increased costs for patients. The integration of the proposed measures facilitates the consistent screening of patient social needs and incentivizes providers and health care delivery systems to navigate patients to address those social needs and to evaluate the impact of those efforts on patient health outcomes. These efforts are needed to identify and eliminate health disparities and work towards health equity.

Massachusetts Child and Adolescent Health Initiative

The Child and Adolescent Health Initiative is a multidisciplinary coalition in Massachusetts seeking to improve care and outcomes for children, with a primary focus on working with MassHealth (the state’s Medicaid and CHIP agency) to assure that MassHealth insured children and their families get the care they need to optimize outcomes.

How would the measure add value?

Assessing health related social needs is an essential step in providing appropriate services to patients/beneficiaries. This assessment enables providers and their health care organizations to then ascertain whether the patient desires assistance in addressing identified needs and, if they do, link them to appropriate and effective services. The tally of needs in a population also points to the broader social needs in a community and can lead to interventions to address the root causes of those needs (what the World Health Organization considers the social determinants or social drivers of health). These are the two strategies being explored in the Accountable Health Communities (AHC) model by CMMI. Given the importance of social needs in influencing both short and long-term health, regular assessment by health care provider organizations in order to take action is a core element of high quality care. Equity is also one of the core dimensions of care as defined by the National Academy of Medicine; key aspects of promoting equity in care include assessing and acting upon social needs and assuring that other aspects of care are not contingent upon the level of social need.

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Asking about social needs requires sensitivity from the provider and candor from the respondent. In addition, as with any interview/survey/screening question, the precise way in which a question is worded produces different results. The cacophony of screening tools related to social needs produces confusion for patients, providers, health systems and others. The use of a consistent, valid, culturally appropriate set of screening questions will lower the burden on providers, produce more meaningful data, and also enable comparisons across providers and systems.

Although the specific information about the measure provided with this MUC list is quite limited, the measure used in the AHC correlates well with at least one other measure of social need for most of the dimensions. The assessment of housing taps different dimensions than the housing instability measure developed by Children's HealthWatch, but nonetheless appears useful.

We note that the specifications indicate the measure applies only to beneficiaries over 18. Understanding that this measure is being considered for use in Medicare programs at this time, we nonetheless note that most of these indicators of social need (food insecurity, housing quality and instability and utility challenges) apply to all the members of a family or household and not simply the person answering an assessment. The information obtained through these assessments should be linked to, and services provided for, those other household members—particularly children who are most vulnerable to the harmful impact of these types of adversity. Similarly, we would want performance measure reporting to be stratified, or reported separately, for children and adults. In addition, although this approval is in the context of Medicare, the measure may be appropriate to ultimately include in the Medicaid Adult and Child Core Measurement Sets and be accompanied by guidance for states in their efforts to standardize these data in both child and adult populations.

•Do the benefits of the measure outweigh the burden of data collection or reporting?

Screening for social needs should be a routine part of care, particularly for, but not restricted to, primary care. The emergency department is also a high yield location for such screening, and is the location that Children's HealthWatch employs in its research. Implementing screening for social needs imposes only marginal burden if systems are already established for other forms of screening (e.g., developmental screening in children, screening for depression in others). As with other forms of screening, screening for social needs only becomes useful for patients if the screening is confirmed by additional inquiry, if the patient desires follow up and if the patient is provided with an effective intervention.

Mechanisms for tracking who has been screened will require effort to establish. Such a mechanism should not be burdensome if fields in electronic health records capture that a screen was performed. Given the importance of assessing and addressing social needs, the benefits outweigh any such burden.

•For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

MassHealth requires that Accountable Care Organizations report on the proportion of each ACO's enrolled population that is screened for social needs, although the state does not specify a particular instrument for screening. The measure is now used for public reporting and may be used as part of payment purposes in the future. We recommend that this proposed measure be used for public reporting and as part of a payment system, and also that individual organizations use it for QI initiatives. Certification systems such as specialty board maintenance of certification programs could also

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incorporate this into their QI modules.

The implementation challenges are noted above; a mechanism for administration of the screening must be developed with appropriate privacy protections, availability in multiple languages, and sensitivity to the concerns of those without documentation. Nonetheless, many studies have confirmed that patients welcome these inquiries and view them as a positive indicator of provider concern, particularly if they lead to follow up conversations and action.

OCHIN, Inc.

These measures are essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes. This enables the clinical team to identify structural barriers to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care (for example, transportation). Care teams would also be able to identify areas of need in their patients, and focus interventions and outreach based on this context.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting to the extent providers are able to identify optimal workflows and staffing to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, estimates that 1 in 3 women has experience IPV, but disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, I would recommend not including IPV in the current measures. I would be more supportive of a separate additional measure for IPV focused on the provision of universal patient education.

OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to begin with the domains of housing, food insecurity, and transportation as “core” domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at UCSF that finds these four domains (housing, food insecurity,

transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, I see these as the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations, or added as more evidence about the relationship between SDOH and health becomes available.

Premier, Inc.

Premier conceptually supports adoption of this measure. However, we would encourage CMS to work with stakeholders to develop a measure that appropriately assesses whether providers are administering screenings for social needs. For example, some providers may only conduct an initial screening on all patients to identify a subset of patients for whom a full social needs screening would be appropriate. Greater clarity is needed around how CMS is defining screenings, since there is no standardized tool. Finally, CMS should not move forward with the measure until it has received endorsement.

North Carolina Medical Society

NCMS is North Carolina's oldest professional organization, including nearly 12,000 members and a network of influential partners extending from county medical societies and specialty societies across the state, to the state legislature and Department of Health and Human Services (NC DHHS).

Consistent with our mission "to provide leadership in medicine by uniting, serving and representing physicians and their health care teams to enhance the health of North Carolinians," NCMS has long recognized and committed to act on the social drivers of health (SDOH), which directly impact health outcomes and health care costs.

On this basis, NCMS strongly recommends that the Measurement Application Partnership (MAP) move forward two measures forward through the regulatory review process: Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136).

NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health care providers have been taxed as never before.

We recognize the strong alignment between physicians and patients about the importance of addressing SDOH. Focus groups we have conducted with our partners show striking agreement among North Carolinians (across race, gender, income, political affiliation, and geography) on what they need to be healthy, with all the focus groups choosing to spend more money on food and housing than on health care. Focus groups with NCMS members echoed these findings, with 100% of participating physicians indicating that some, many, or all of their patients are affected by social conditions.

Our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live

in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and laying the foundation to invest in those community resources necessary for health.

Citations: https://www.healthaffairs.org/do/10.1377/hblog20210429.335599/full/

UniteUs/NowPow, a wholly owned subsidiary of UU

Overall, Unite Us supports including measure 134 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. Including these measures will encourage clinicians/clinical staff to screen and track social drivers of health. We recommend that additional measures should be considered that evaluate if beneficiaries who screened positive receive services to address their social drivers of health in a timely manner. Assessing without addressing does not improve quality in a meaningful way. While we encourage the use of social driver measures, the Unite Us team have some concerns regarding the measure implementation, methodology and process. It is not clear whether all domains would need to be assessed (e.g. financial insecurity and housing and utilities, etc.) or any one of these domains could be assessed to meet the measure. It is unclear if 80% beneficiaries screened means 80% of people had at least one of these domains assessed (but some had financial insecurity assessed, some were assessed for transportation, or all were assessed for interpersonal violence and nothing else) or it means 80% of people had all of these domains assessed. The Unite Us team advocates for the latter approach, as it is a higher standard.

Health Care Without Harm

December 9, 2021

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and

MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease and death. Climate change, the COVID-19 pandemic and

increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post November 30th: 1) More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes; 2) About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year; 3) More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness; 4) If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people; 5) Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection; 6) And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

When addressing issues such as food insecurity, housing instability, climate change, lack of

transportation, and exposure to toxics in our air, land and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen, President, Health Care Without Harm & Practice Greenhealth

For more information, please contact: Emma Sirois, National Director, Healthy Food in Health Care Program, esirois@hcwh.org

MS State Department of Health

This measure will not only determine what the patient's basic needs are, but it was also help in determining what programs/services are lacking in that patient's community. It will also help determine what other social determinants are playing a positive or negative role in the patient's health (mental and physical). The benefits outweigh the burden of data collection because it well help to improve the overall health in communities in identifying service gaps and referring patients to services they need. My program is in the process of screening for social determinants of health in working with expectant and parenting families. No current implementation challenges because the assessment is already built in the electronic health record database.

Phreesia

Phreesia applauds CMS's commitment to screening for social drivers of health and identifying the percent of beneficiaries who screen positive. However, there is no discussion of how the data should be collected. While the proposed IQR measure MUC2021-106 would require hospitals to train staff on health equity screenings, no measure included in the 2021 MUC List include an explicit reference to how such data should be collected. Furthermore, none of these data collection methods for social drivers or those in the equity domain specify the crucial importance of self-reported data from patients.

Self-reported data is fundamental to achieving higher quality care and an optimal patient experience. Experts agree that self-reported data is the most effective approach for data collection. Additionally, many health systems are now initiating or scaling SDOH screening, where self-reporting is crucial. Most are accomplishing this through verbal collection programs, though our experience shows that digital screening tools are by far more effective in accurately capturing patients' demographic and social needs information.

In general, failing to effectively capture patient demographic and social needs information has the potential to erode trust in the healthcare system among minority groups whose trust is already significantly low. However, when given the opportunity to input their own demographic data, we have found that patients are able to accurately provide key information and can play a key role in improving their own care by closing gaps in data. Phreesia encourages CMS to move providers to screening

methods that include an explicit focus on patient self-reported data.

CyncHealth

The proposed measures are a step in the right direction. As a health information exchange (HIE), we recognize that these measures add value to both the community and providers. They allow for the community to become more aware of the social needs that are prevalent in the community, and for providers to have better data for reporting. This increased awareness and data allows for an improvement in cross-sector partnerships to occur that empowers providers and communities to collaborate and advocate for polices that support equity in their communities.

As an HIE, we would use the measures to do regulatory reporting on behalf of the providers we serve. The benefit of these measures will be determined by the effective implementation of the measure. The biggest challenge to implementation of these measures is a lack of standardization. There should be serious consideration given to adapt a universal screening tool, so that outcomes can be measurable and consistent across the board. A failure to adapt a standardize screening tool will result in inconsistent outcomes. Currently depressions screenings are standardized to the PHQ and that allows for measurable and consistent outcomes to be reported. The same level of standardization needs to be applied to these proposed measures. The consistency of measurable outcomes that standardization will provide will enable the development of a good tool and provide a real-world benefit that outweighs the burden of data collection or reporting.

National Produce Prescription Collaborative

December 9, 2021

To: Members of the NQF: Measure Applications Partnership From: Members of the National Produce Prescription Collaborative (NPPC)

*SUBMITTED TWICE *

RE: Support for Driver of Health Screening Rate (MUC2021-136)

*Re: Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the 2021 CMS MUC list, and recommend that you move them forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle.

Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its

“measures under consideration” list this year. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center’s Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through our federal health programs.

As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people’s diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long standing burden of diet-related chronic disease. Unfortunately, these diet-related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

If approved, this measure would apply to two key Medicare programs — the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — and improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, we see adoption of this measure as a pathway for Produce Prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs

The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country. A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions improve improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the

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Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers. Having DOH measures available to screen for food insecurity will help these government-sponsored health plan practitioners deliver on the growing promise of food as medicine. For example: In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity. Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercised regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020. Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare, and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward for consideration.

About NPPC

The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and who are referred by a healthcare provider or

health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

Harvard FXB Center for Health and Human Rights

I believe there is much value in collecting this data. However, I do wonder if there is a complimentary mechanism/data collection standard that could be implemented to understand if a referral or connection has been made to address those needs identified. Without this additional yet complimentary data collection, this data collection standard alone could also promote an ethical dilemma that emphasizes data collection over both resource connections and the investment in the community infrastructure to meet identified resource gaps. In 2016, "Dr. Alvin Garg, Dr. Renee Boynton-Jarret, and Dr. Paul Dworkin outlined in the JAMA Network that screening for any condition in isolation without the capacity to ensure referral and linkage to appropriate treatment is ineffective, and arguably unethical."

Also, with this standard, I hope that CMS will think about how this new data collection influences the social determinants of health industry. In the recent research article by Zachary Goldberg and Dr. David Nash "For Profit but Socially Determined: The Rise of the SDOH Industry," an emerging for-profit industry focused on social determinants of health has received over $2.4 billion dollars in funding and is valued at $18.5 billion dollars.

As studies show, racial/ethnic minorities are more prone to experience disparities in social determinants similar to traditional health disparities. Therefore, as SDOH technology platforms extract data, there is a higher likelihood of collecting more SDOH data or resource gap data on BIPOC communities. It is important to understand that BIPOC communities make this data valuable and, in turn, makes the technology platform/vendor platform. The market is even seeing SDOH technology companies participating in a monopoly to gain influence in this sector. These companies see extreme profit gain at the cost of BIPOC pain; that pain is revealed in BIPOC SDOH data. If one claims to be an advocate of racial justice, one cannot align with this approach--nor the technology vendors, health care systems, and other stakeholders that push this approach. This SDOH deficit data extraction approach ultimately furthers racial capitalism, which is established upon extracting social value and economic gain from the racial identity of others. Racial capitalism highlights the direct relationship between racial exploitation and capital gain, and many stakeholders see this currently in the SDOH sector. These technology companies will even publicly acknowledge the existence of structural racism while engaging in acts of profiteering off of structural racism.

Community members, especially BIPOC community members, are often least prioritized in these tech-forward SDOH interventions as most of these technology-forward approaches fail to see the patient/clients of social service organizations as the ultimate end user.

The primary reason for this predatory behavior stems from the healthcare sector's dictation of the return on investment case that is deemed most important. Often patients are seen as a high risk group, and many health systems, health plans, and others are interested in the mere collection of this data to understand this population more. The data collection normally benefits stakeholders of power for health system focused analyses, like understanding the relationship between essential resource needs or resource care gaps (like food insecurity and housing insecurity) and healthcare metrics, like utilization

and cost. Even more, this influx of a new data source can facilitate machine-based learning or predictive analyses that aim to reveal new learnings about the patient/client group. However, this machine-based learning or predictive analyses without an equity or anti-racist approach can have harmful effects marginalized communities. In Automating Inequality, Virginia Eubanks investigates how data mining, predictive risk modeling, and algorithms can actually be used to punish historically marginalized and socioeconomically disadvantaged individuals and groups. In the collection of SDOH data, patients are rarely fully informed nor provide consent on how data is used within a SDOH intervention and even more so after their intervention encounter.

We, as a sector, must ask ourselves as stakeholders in the SDOH space:

1) If patients and clients knew our approach to data use fully, would it yield more trust?
    a. If not, how do we create structures of good stewardship and trust around our clients'/patients' SDOH data?
2) How do we have processes of informed consent and informed refusal with the collection of SDOH data, particularly given the predatory/structurally racist nature that seems to be present in the SDOH industry currently?
3) Additionally, are we using SDOH data to create, reinforce, or further perpetuate bias? . If so or if we are unsure, how do we create accountability structures to ensure the creation, reinforcement, perpetuation of bias does not occur (or at least limited)?

With the implementation of these new data collection standards, which I believe can be beneficial, I believe there is a need for further work to happen to ensure that the data collection is anti-racist. Without this equity/antiracism work, I fear how SDOH data will be used.

Social Interventions Research and Evaluation Network at the University of California, San Francisco
December 9, 2021

National Quality Forum Measure Applications Partnership Dear Measure Applications Partnership Committee Members

As national leaders of the Social Interventions Research and Evaluation Network (SIREN), a center at the University of California, San Francisco dedicated to elevating and strengthening evidence related to programs and policies that can support health care systems to meaningfully deliver social care and as leading national experts in this evidence, we welcome the opportunity to comment on the social risk screening measures (MUC2021-134 and MUC2021-136) currently being considered through the MAP process.

We are excited to see federal level interest in quality measures related to social determinants of health (SDH) and social risks since these factors have been closely tied to health and health care utilization outcomes and equity. Incorporating feasible and impactful measures will help to signal the importance of assessing and addressing patients' socioeconomic risks as a critical part of a comprehensive strategy for improving care quality and outcomes.

We very much appreciate the potential advantages of increased recognition of patient-reported social risks in health care settings. Awareness of social risk may inform a range of interventions that have the potential to improve care quality, patient health, and reduce health costs. These interventions have

been described in the 2019 National Academy of Sciences, Engineering, and Medicine report on Integrating Social Care into the Delivery of Health Care to Improve the Nation's Health. They include not only strategies to connect patients with social services, but also strategies to tailor or adjust medical care decision-making based on patients' social contexts and opportunities to strengthen data that informs community level investments and advocacy.

Recognizing the potential advantages of implementing quality measures in this area, we recommend moving forward with these measures with some modifications to address concerns detailed below. We also hope that this is just the first step in building out a robust set of quality metrics that measure, guide, and reward clinicians' and hospitals' work to improve patient outcomes by identifying and addressing social risks as part of high quality clinical care.

Although we support moving forward with these measures, we share below some key concerns based on our knowledge of the research evidence and our experiences as practitioners (for Drs. Gottlieb and Lindau), as well as recommendations for how to address these concerns.

1. Could social risk screening cause harm that outweighs benefit?

Although there is abundant evidence that social factors strongly shape health and health care outcomes and inequities, it is not yet clear whether social screening (assessing) without subsequent interventions (addressing) actually improves outcomes. Studies have found that many patients understand how social conditions relate to health and well-being and believe that screening in health care settings is appropriate. At the same time, patients have voiced important concerns about potential negative consequences of sharing information about social adversity in health care settings, including concerns that the information could be used against them, worsen feelings of stigma, and exacerbate real or perceived bias/discrimination. Where, how, and by whom screening is conducted and data are used will influence patients' experience and the quality measures. On the whole, evidence suggests benefits outweigh risks in contexts where needs are assessed in ways that are patient-centered and minimize risks for stigmatization and discrimination. In the future, an additional patient-centered and patient-reported measure might be considered about the experience of screening.

2. Are there drawbacks to having measures related to screening without measures related to acting on identified needs?

Incentivizing screening through quality measures without also incentivizing action on identified concerns may lead health care organizations to attend to assessment over intervention, which may have benefit for calculating risk-adjusted payment, but is unlikely to meaningfully change health outcomes. In a worst case scenario, screening that does not yield risk-adjustment could result in 'creaming' or strategies to limit service to individuals or communities with higher socioeconomic risk. At the same time, although several NIH-funded randomized controlled trials with a diversity of urban and rural target populations (e.g. families with hospitalized children, dementia caregivers, older people with diabetes, adults and children with cardiovascular disease risk) are ongoing, research has not yet provided clarity about what types and what intensity of actions are most likely to improve outcomes. Ideally the screening-focused QM will contribute to more innovation and evaluation in the intervention space. This learning should contribute to measure development around strategies to hold health care organizations accountable for acting on collected social data. One possibility is to consider revising the second proposed QM (#136) to reflect a measure of change in the screen positive rate.

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3. Are these the right social domains to include in a social screening quality measure?

In 2014, the National Academies recommended routinely incorporating information about financial strain/insecurity in EHRs with follow up assessments conducted only as needed around basic material needs such as transportation, utilities, food, and housing. This recommendation is not reflected in the proposed measures. Though the four social risks related to socioeconomic security (food insecurity, housing instability, transportation problems, and utility security) included in the proposed measures may each be relevant to health and actionable, it may not be maximally efficient to screen for each of these until an overarching assessment of financial strain is conducted; on the other hand, unpublished data suggests that needs disclosure may be higher in response to individual topics. If these measures move forward as they are, in the future research on likelihood of disclosure should be revisited and the measures should be modified. Additional topics related to basic material needs also should be strongly considered, e.g. digital access (a topic of whose relevance to health disparities is rapidly changing), employment, legal needs, and childcare affordability/access.)

4. Interpersonal violence screening poses unique concerns and opportunities

Screening for interpersonal violence raises a number of unique concerns, including but not limited to the distinction between interpersonal violence and intimate partner violence. One consideration would be to require that if IPV is the only measure a health system is assessing, in order to meet the quality standard, they must also include at least one other driver of health measure from the list of other included domains.

5. The proposed measures would benefit from more detailed specifications.

We would like to highlight two areas that are not clear about these measures: ○ It is our understanding that measure 136 (screening) is meant to only count beneficiaries screened for all five risks (vs. any of the five risks) and that the screening positivity measure (134) is meant to count beneficiaries with at least one of the needs (not only those who have all five). However, the way the measures are defined do not make this explicit. ○The measure definitions also do not specify whether clinicians and hospitals can use any screening tool or approach or whether there is a required set of questions or tools that should be used. Despite hoping for future standardization, we currently would recommend allowing flexibility in how different social domains are measured because since there are a variety of assessment tools already in use across the country. We recommend that these definitions be clarified as the measures move forward in the process.

Summary

In summary, based on our knowledge of the research evidence in this space, we recommend that these measures mover forward but with the following modifications:

• Clarify the definitions of the measures

• Provide guidance about how to conduct screening in a way that is patient centered, maximizes confidentiality, and minimizes risks of stigmatization and discrimination. Also consider adding measures of patient experience in the future.

• Ensure the measures provide clinicians and hospitals flexibility in the screening tools and approaches

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used.

In addition, in the future we recommend adding measures focused on the actions that providers and hospitals can take to improve patient outcomes based on screening information, since those actions are what will lead to benefits to beneficiaries.

We thank NQF for providing this opportunity to provide feedback about this important and growing part of high-quality patient care. Please reach out to laura.gottlieb@ucsf.edu if you have any questions about these comments.

Sincerely,

Caroline Fichtenberg, PhD, University of California, San Francisco Taressa Fraze, PhD, University of California, San Francisco Laura Gottlieb, MD, MPH, University of California, San Francisco Danielle Hessler Jones, PhD, University of California, San Francisco Stacy Lindau, MD MAPP, University of Chicago

United Way of the Mid-South

We welcome this opportunity to submit our comments related to the proposed addition of two new proposed quality measures related to social risk screening:

- Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136)
- Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134)

In 2016, the United Way of the Mid-South (UWMS), based in Memphis, Tennessee, launched Driving The Dream (DTD), a resilient human services ecosystem that aligns and better integrates the local human services, represented by 82 agencies, with the goal of connecting under-resourced families to an array of supportive services as well as clinical healthcare to improve their overall health and wellbeing. As an organization, we have worked deeply in this space and understand the nuances and complexities of coordinating and aligning clinical care and social services. As a former state public health commissioner and practicing physician, I personally understand firsthand the social and economic challenges families face when it comes to promoting their own health and the health of their children and other family members.

Given this experience and exposure, UWMS believes the introduction of these measures is a critical step in bridging the gap between clinical services and social services that address the socioeconomic and environmental factors, which as evidence supports contributes to 50% of a person's overall health and wellbeing. Adoption of these measures will provide standardized data that begin to provide insights into the depth and breadth of social barriers that contribute to poor health outcomes. Additionally, with the ability to disaggregate by demographic characteristics, it will make visible the social factors driving or inhibiting health, particularly for communities of color. Equipped with this data, human services providers can better direct existing resources to be responsive to gaps, while also more effectively making the case for additional services that may be needed.

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While these measures are just a first step in terms of diagnosis, adoption of these measures has the potential to drive greater awareness among clinical providers regarding the interconnectivity of physical health and underlying socioeconomic conditions. That awareness has the potential to incentivize more formal partnerships between clinical care and social service providers, all with the ultimate goal of improving patient health and wellbeing.

We are in full support of the adoption of these measures, however, we do raise one potential implementation challenge, as it relates to screening. There are a number of social determinants of health screening tools that have been adopted and in use by both clinical providers as well as social service providers. Understanding if there are specific validated screening tools that must be used to screen and diagnose these conditions is a potential area for further exploration and discussion.

Should the review committee have any follow-up questions or additional discussion, we would be more than happy to further contribute insights and related guidance.

Sincerely,

Kenneth S. Robinson, M.D.

Reinvestment Partners
I'm writing in support of MUC2021-136. This measure represents a crucial step towards addressing racialized health disparities and meaningfully addressing social drivers of health. Our agency implements SDOH programs and feel strongly that these measures would generate important data that we would use to inform our program delivery and improve our ability to serve patients in need.

Thank you for considering.

Signify Health
To Whom It May Concern:

We appreciate the opportunity to offer comments pertaining to the referenced MUCs. By way of background Signify Health is a value-based care company that brings together a unique combination of services to reduce the costs and improve the quality of health care provided to beneficiaries of public and private health plans. We are a leading provider of technology-enabled, in-home assessments, complex care management, and SDOH services. We believe deeply that health flourishes in safe homes and connected communities. Every day, across the U.S., we deploy the nation's largest mobile network of duly licensed clinicians to support people where they are – in their homes, residential facilities, and communities. We take the time to fully understand their lives and use these insights to connect them to the medical and social care they need most.

Our comments apply to both proposed Measures.

> How would adding this measure add value? How would the measure improve patient outcomes?
>
> The proposed measures for data collection and reporting represent the first and necessary step to assessing the scope and scale of social needs for a population and understanding its true impact on health outcomes. Subsequent analyses of the resulting data

can assist community-based organizations, payers, providers and policymakers in designing programs that are discrete, modifiable, meaningful, and impactful in addressing social determinants of health.

Do the benefits of the measure outweigh the burden of data collection or reporting?

Yes, however financial incentives will likely be necessary in order to accomplish broad data collection efforts. In order to relieve the associated burden, CMS could consider creative/innovative ways to collect the SDOH data to reduce burden on hospital and physician care teams. However, it is important to recognize the obvious: not all populations seek care in the traditional health system. If a hospital or physician is the sole data collection site, we are missing out on a significant population with unmet SDOH needs that could exacerbate a clinical condition that results in a subsequent hospital admission. To ensure more comprehensive data collection, public and private payer (Medicaid, ACA, MA, Medicare Supplement private insured) enrollment processes could be expanded and utilized to collect **standardized data**. Government grants could also be made available to organizations such as the United Way and other community-based entities that interact with community based organization to enlist their aid in collecting and submitting SDoH data.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

As an organization, Signify Health collects SDoH data on a limited basis. We utilize this information to design programs that improve access to community-based services and to improve health outcomes.

Are there implementation challenges?

Yes. From a technological perspective, ensuring the security and privacy of data collected as CBOs are not covered entities under HIPAA; and the absence of a standardized data set; and operationally ensuring appropriate and culturally sensitive training of staff necessary in order to build patient trust. Importantly, the need for financial support to cover the required additional resources, time and effort to comply fully.

Thank you for your consideration.

About Fresh, Inc.

Thank you for the opportunity to provide comments on the 2021-2022 Recommendations for Measures Under Consideration. We were happy to hear that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the2021 CMS MUC list. We are writing now to recommend that you move those forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle. We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we up lift data, health insights, and community voice to meaningfully integrate food access in to the delivery of

quality care. We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes . Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system. The Physicians Foundation (directed by 21 state and county medical societies across the country) has submitted to CMS two DOH measures focused on screening for food insecurity, housing instability, transportation, utility needs, and interpersonal safety. These measures represent the foundation for future measures focused on ensuring patients secure the resources they need to be healthy and enabling community investments required for health. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities (AHC)model. AHC has now screened ~1 million beneficiaries, with 69% of those who are navigation-eligible reporting food insecurity (the highest reported need).These DOH measures have gained significant traction and momentum in the healthcare sector. The Commonwealth Fund and the Blue Shield of California Foundation recently published a blog, focused on these measures as a crucial milestone on the path towards health equity.

The Physicians Foundation also published a Modern Healthcare op-ed calling for the measures' adoption, given the profound impact of DOH on health outcomes and costs, as well as physician burden and burnout. Including food insecurity as a quality measure in the major federal healthcare programs(Medicare and Medicaid) via these DOH measures is a crucial prerequisite for CMS, states, or commercial payers to pay for access to healthy food, not as a pilot or initiative, but as a standard health benefit. Absent such measures, the impact of DOH will remain functionally invisible in federal healthcare policy making. Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch

Chief Program Officer

Josh Trautwein

Chief Executive Officer

January 10, 2022

To: Members of the NQF: Measure Applications Partnership

From: About Fresh, Inc.

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RE: Support for Driver of Health Screening Rate (MUC2021-136)

Thank you for the opportunity to provide comments on the 2022 draft recommendations offered by the Measure Applications Partnership (MAP) Clinician, Hospital, and Post-Acute Care/Long-Term Care (PAC/LTC) Workgroups.

We are writing to offer our strong endorsement of the MAP Workgroup's support for the SDOH measures for MIPS. In addition, we urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the Hospital Inpatient Quality Reporting Program (HIQRP).

Publication of hospitals' screen positive rate would (1) improve healthcare transparency; (2) enable more targeted, data-driven community investments; (3) signify hospitals' familiarity/expertise regarding these issues; and (4) inform and strengthen quality improvement activities, including those addressing healthcare inequities.

We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we uplift data, health insights, and community voice to meaningfully integrate food access into the delivery of quality care.

We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes1. Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system.

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Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch, Chief Program Officer

Josh Trautwein, Chief Executive Officer

Providence

This would increase the identification of patients with food insecurity, help connect them to resources and improve health and quality of life. The benefits outweigh the burden. The measure would be used for QI. The main implementation challenge is connecting patients to resources and closing the loop that the resources have been received.

Providence Health & Services Oregon

In the last decade, social determinants of health have become increasingly recognized by health care as a critical piece impacting patients' health and well-being. In fact, some sources share that as much as 70 percent of a person's health is influenced by social, economic, and physical factors like food, housing, and transportation. Offering social care screening and interventions allow clinical staff to feel more empowered to fully care for their patients, and patients to receive comprehensive care incorporating social and structural factors into their care plan, allowing clinicians to care more thoroughly for the whole person.

Further, those who experience the greatest burden of social needs, are often among the most underrepresented and marginalized, including communities of color, older adults, people with disabilities and those living in poverty. Offering and standardizing social needs screening across Medicare beneficiaries will allow us to better identify and address inequities and disparities in care among these populations. Screening all beneficiaries also removes any implicit bias within individuals and organizations, removing any assumptions of who is perceived to have social needs. This is critical because older adults especially are less likely to express social needs due to societal stigma, as well as personally held beliefs that others need the services more than them. We cannot deliver high quality care, truly caring for our patients, if we cannot identify barriers, like social needs, that may impact care plans and overall health.

While systems change is difficult, especially during the era of COVID-19, and adding more to clinicians' plate is a challenge to consider, this work is too important to the health of individuals, families, and communities overall not to act. Having participated in the Accountable Health Communities grant, and other national initiatives that include social needs screening for five years, we have seen clinical infrastructures to support this work significantly evolve. Most electronic health record systems now have some capacity to document social needs screening, making it easier to capture and report on the data, as well as use at point of care in care planning and care coordination. We have been able to better understand our patients' priorities, as well as challenges to managing their health, and take action to meet their needs. Based on time studies completed using both in-person and phone-based social needs

administration, we have found it adds minimal time to both rooming and overall clinician staff time and documentation. Not only do frontline staff find it adds minimal time to rooming, patient encounters and documentation, but patients are often positive to the screening itself, even when they do not experience social needs themselves.

Based on our experiences, the greatest challenge to implementation and adoption is that it is not a required metric. Staff do not find the process complicated, and they believe it is important, but because this work is currently more in line with our organizational values rather than billing and reimbursement, it can be hard to prioritize over other required work. With the number of requirements expected of clinical teams, doing "optional" work can be the hardest to standardize and adopt. Clinics often prioritize the work that is required for reporting or is tied to billing. Without social care screening being a required quality measure, it is difficult to standardize across all care settings. To date, adoption has been most successful with clinical teams that have this work tied to national grant initiatives or aligning with CPC+ initiative and/or patient centered primary care medical home standards.

As an organization, identifying and addressing social needs aligns with Providence commitment both as a population health company prioritizing value-based care, but also aligns with our mission and vision of creating healthier communities and easing people's way. As a mission-driven health car system, we have recognized that social needs are critical from our founding. Our Sisters of Providence started their care 160 years ago by opening orphanages and food pantries, before building a hospital. They understood the importance of social needs impact on health and well-being, and we continue to honor their vision.

Providence is committed to being a partner in moving social needs screening forward and we thank the committee for their consideration and continued support.

Cerner

With changes in regulatory requirements and a shift towards a value-based paradigm, it is now more important than ever to have complete data. As data becomes more complex, we have the ability to extract multifaceted insights and provide actionable analytics to organizations striving to satisfy the triple aim at the core of healthcare reform - promoting better health, providing better care, and reducing cost.

To excel in population health management, you need to understand how patient characteristics and contextual factors, external to the care delivery process, impact your patients. We help you to better understand how these characteristics affect segments of your patient population, optimize care delivery, understand variation in outcomes related to SBDH burden, excel in value-based care and achieve health equity.

Yale School of Public Health

Cancer incidence rates in Connecticut are well above the national average with the greatest overall burden on African Americans, Hispanic/Latinos, and those of low socioeconomic status (1). Recognizing the need for cancer control across the continuum, the Yale Cancer Disparities Firewall Project of the Yale Cancer Center (funded by Bristol-Meyer Squibb Foundation, co-sponsored by the Yale Cancer Center and Yale School of Public Health) uses an innovative approach to engage community residents prior to their need for cancer-specific services. In order to develop positive community relationships and facilitate institutional knowledge and trust, the Firewall Project offers "in-home" navigation to match high risk community members with social needs resources and providers as well as health education

about cancer prevention and early detection and free cancer screenings. Our navigation services are distinct from conventional cancer navigation programs in three important ways: 1) a cancer diagnosis is not needed to qualify for or participate in Firewall programs, 2) conceptualized as wrap-around support, our project screens and assists community residents with social needs, and 3) our navigation services are provided telephonically and electronically allowing participants to receive resources or assistance in their home and community or other setting that is convenient for them.

Outcomes to date relevant to the collection of social determinants of health data as proposed: During a pilot project, 200 “healthy” people were offered social determinants of health screening at public events targeting specific neighborhoods or populations; 75 completed a telephonic SDOH screening and cancer risk factor intake survey. Among those with completed screenings 69% were identified as having one of more social need and significant percentages were referred to social services providers to help address food insecurity (42%), housing instability (39%), transportation challenges (32%), and utility assistance (29%). Approximately one third of the program participants were able to complete cancer screening visits or other medical appointments (including tobacco treatment visits) due, in part, to social needs support facilitated by the navigation program despite pandemic-related scheduling challenges in our state.

What we have learned: Even in times of uncertainty such as during a pandemic, screening for SDOH helped build trust among community members and improved potential points of engagement for health care as all of those who failed to complete intakes participated in conversations with community health educators about prevention, cancer screening or healthy lifestyles. Among those with identified social needs, those who screened positive for food insecurity and transportation challenges were able to be assisted in ways that helped them complete cancer screening or other medical visits. Whether patient outcomes were improved is something we would assess longitudinally. If screening rates are maintained or increased over time, however, one would expect overall health (e.g. earlier stage diagnoses, cancer risk awareness, broader availability of treatment options) to also improve. Additional follow up and analyses will be needed to determine statistical relationships between SDOH screening and health variables; however, the screening questions.

The SDOH screening questions were acceptable to participants and easy to administer using an electronic interface.

The measures have been used as part of research or pilot implementation programs focused on reducing cancer disparities in prevention and screening among underserved and racial/ethnic minoritized populations. Our selection of a screening tool was bolstered by CMS use of similar SDOH items in the Accountable Health Communities (AHC) demonstration projects (2,3). The SDOH screening assess social needs in five areas: food insecurity, housing instability, transportation challenges, utility payment challenges, and interpersonal safety (2,3). The screening items are also aligned with Healthy People 2030 SDOH goals and CMS’ Meaningful Measures 2.0 initiative.

Implementation challenges at the health care system level include personnel and workflows for data collection, consistent data collection across the system and determining ways for data to be reported and proactively used by the health care system. At the provider level, implementation challenges include consideration of when SDOH screening questions should be asked within a visit workflow, by whom and appropriate follow up actions for patients who screen positive. Other implementation

challenges include connecting patients with agencies that can help address social needs and communicating to patients and the public about how such screening data may be relevant to their health care and health outcomes. Despite such challenges, implementation of social needs screening may positively impact quality and health equity efforts by reducing the impact of unacknowledged and unaddressed social needs on health care outcomes.

This comment is issued as conditional support for rulemaking for MUC 2021-136 for IQR and MIPS pending NQF endorsement. In order for health care systems and providers to begin assessing and monitoring social needs and their impact on health, starting with screening is an important first step.

(1) State Cancer Profiles. Connecticut: Accessed at: https://statecancerprofiles.cancer.gov/quick-profiles/index.php?statename=connecticut. Created by statecancerprofiles.cancer.gov on 01/04/2022 1:46 pm.

(2) Centers for Medicare & Medicaid Services (CMS). The Accountable Health Communities

Health-Related Social Needs Screening Tool. Accessed on 1/4/22 at: https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf.

(3) United States, U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. (2017, September 05). Accountable Health Communities Model. Link: https://innovation.cms.gov/initiatives/ahcm.

The ideas expressed here are those of the author and do not reflect the positions of the institutions with which she is affiliated.

Sakinah Suttiratana, PhD, MPH, MBA

Medical Sociologist/Chronic Disease Epidemiologist

Mass General Brigham

My name is Allison Bryant, and I am the Senior Medical Director for Health Equity for the Mass General Brigham health system, an enterprise of some 14 hospitals (including academic medical centers, community hospitals and specialty care facilities), numerous outpatient facilities and urgent care sites. We serve over 1 million adult primary care patients across the region, with an incredible diversity of social background and health care need.

Those of us who have the privilege of delivering healthcare know that all the things we say we want to do, like building strong relationships with our patients; achieving health equity; reducing costs; and addressing staff well-being, depend on our recognizing the realities of the lives our patients live outside the proverbial “4 walls” of our institutions. We have seen how critically important unmet social needs such food insecurity or housing instability have escalated and been so dynamic in the context of COVID.

Unfortunately, however, we know that under federal payment and current quality frameworks, our health systems code, screen, measure and risk-adjust for conditions like diabetes, but not for food insecurity – even though diabetics who are food insecure have worse health outcomes and cost the system a great deal more per year than those with access to healthy food. At Mass General Brigham,

alongside other healthcare delivery systems across the country, have committed to screen for and address health-related social needs. As committed as we are to this work, we are doing so without the benefit of any SDOH measures in any federal payment model, including within Medicare or Medicaid.

In our health system, we are committed to screening annual for SDOH among members of our Medicaid Accountable Care Organization, in the context of primary care. Under our United Against Racism campaign, we have scaled up these efforts in a payer-blind manner, in 23 communities with the greatest need, and leverage a fantastic and expert workforce of community health workers to assist our patients in meeting SDOH needs.

We are expanding this work to engage specialty care environments such as maternity and NICU care, recognizing the absolute importance of meeting social needs at these critical times in our patients' lives. We are also building a program of nutritional equity, to ensure access to healthy foods and medically-tailored meals for patients with hypertension and substance use disorder, for example. This programming will rely on a need for robust screening not just for food insecurity, but for nutritional access more broadly.

Within our network, we have also begun trials of SDOH screening and response in our inpatient spaces, learning that it is not only feasible, but incredibly meaningful for a population enriched for medical and social complexity. Screening for and responding to, for example, food insecurity or financial inability to purchase prescriptions that may impair adherence to care plans is likely to result in improved health outcomes. Similarly, teams in our system have begun to screen for digital access like devices with cameras and working internet at home at the time of hospital discharge, to inform care planning in an environment increasingly reliant on technology.

It is important to note that both of the SDOH measures under review today are critical to make visible the impact of these issues on the lives of patients and the inequities they perpetuate. Given the disproportionate impact of SDOH on people from historically marginalized communities, the equity agenda here is clear; we must recognize providers and institutions for screening their patients and reporting the screen positive rate, to elucidate racial/ethnic disparities in DOH that, in turn, fuel disparities in health outcomes.

Finally, we are aware that there only 3 measures tagged to the domain of "equity" in the proposed slate, and that these being reviewed today are the only patient-level SDOH or equity measures under review. It is all the more imperative that the MAP Committees recommend them. Given what we have learned from COVID, and given CMS's commitment to address health equity, now is very clearly the time to introduce federal payment program measures that recognize the profound impact of SDOH on the lives of our patients, their families and communities.

Respectfully submitted,

Allison Bryant, MD, MPH
Senior Medical Director for Health Equity,
Mass General Brigham
Frederic D. Frigoletto, MD Endowed Chair
Department of Obstetrics and Gynecology
Massachusetts General Hospital

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Associate Professor of Obstetrics, Gynecology and Reproductive Biology
Harvard Medical School

Morris-Singer Foundation

As a primary care physician and Co-Director of the Morris-Singer Foundation (MSF), I am writing in support of two recently-considered measures of social determinants of health (SDOH): Screening for Social Drivers of Health MUC2021-136 (MIPS and Hospital IQR).

The Morris-Singer Foundation is a family foundation committed to pioneering new ways of being and engaging as we address the complex problems of our time. We provide grants to support a range of programs, including several operating on the frontlines of health care. Two in particular give us a unique view into the minds of clinicians: the Relational Leadership Institute at Primary Care Progress and 3rd Conversation by X4 Health. Both programs convene clinicians and administrators in conversations and trainings with each other to supercharge relationality and human connection in our health systems. These rooms tell us without a doubt that clinicians are hungry for SDOH measures that help shift the practice of medicine from the normal litany of required measures, to measuring what matters for health.

That's why I strongly support the screening measures for social drivers of health for both MIPS and the Hospital IQR program (MUC2021-136). Taken together, these are the first-ever social drivers of health measures in any federal quality or payment program.

I strongly urge the MAP to recommend both these SDOH measures. The technical merits of measures are important, but they can also be an excuse for inaction.

We on the front lines of healthcare know that building strong relationships with our patients; addressing physician burnout; achieving better health for all; and reducing healthcare costs depend on our recognizing the realities of our patients' lives, those critical co-morbidities such as food insecurity or housing instability that have only escalated in the context of COVID.

Yet, under federal payment and quality frameworks, the healthcare system codes, screens, measures and risk-adjusts for diabetes, but not for food insecurity – even though diabetics who are food insecure have worse health outcomes and cost on average $4,500 more per year than those with access to healthy food.

Amazingly, there is not a single SDOH measure in any of the federal payment models. Not one.

It's past time for these measures – especially as we physicians continue to witness COVID's profound impact on the physical, psychological, and economic well-being of our patients. We can't keep asking clinicians to address health without also providing tools and reimbursement to understand the known drivers or determinants of health.

One question that has come up is whether these measures will incentivize providers to care for wealthier patients or frustrate patients and providers because they involve screening for SDOH but do not yet require action on the results. Not only do these completely hypothetical concerns reflect a striking degree of cynicism about my fellow physicians and health professionals –they are inconsistent with the evidence from testing of social needs screenings in clinical settings, which shows that providers

will chose to screen their patients and will act on those results.

CMS's largest-ever primary care model, Comprehensive Primary Care Plus, did not include a SDOH screening requirement for about 1,200 practices in the model. But 86% of these practices screened their patients anyway – because they knew that's what their patients needed to be healthy. We must begin to include measures that will enable quality improvement and appropriate payments related for health.

The evidence makes clear that physicians are committed to helping their patients with these issues, and these SDOH measures are key in recognizing, supporting and incentivizing practices that choose to do so.

As burnout skyrockets in the pandemic era, helping medicine measure what matters will be a key strategy in preventing the mass exodus that will threaten our system.

Let us not make any excuses for inaction. I strongly urge the MAP to recommend both these SDOH measures to recognize – for the first time in a federal payment model – the thousands of physicians and other healthcare providers who work every day to understand what their patients need to be healthy and to address these needs.

Sincerely,
Andrew Morris-Singer, MD
Co-Director, Morris-Singer Foundation

Academy of Nutrition and Dietetics

The Academy of Nutrition and Dietetics' (Academy) Strategic Plan has a focus area dedicated to the topic of food insecurity- Nutrition Security and Food Safety. Within that focus area, there are impact goals: Advocate for equitable access to safe and nutritious food and water, and Advance sustainable nutrition and resilient food system. Therefore, the Academy is focused on impacting the health and wellbeing of individuals impacted from food insecurity, a component of the quality measure.

A concern with this proposed measure is it is not outcomes based. What happens with care once the individual is screened? What interventions are proposed to improve care? These outcomes are important so that care is impacted, not just data collected.

Food insecurity and malnutrition are widespread and worsening issues in the United States. Both food insecurity and malnutrition are associated with negative health outcomes and higher spending on health care. Adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgery, and recovery outcomes. Registered dietitian nutritionists (RDNs) have a responsibility to identify and address nutrition and food insecurity.

The purpose of a food insecurity screen, which is a component of the Accountable Health Communities Health-Related Social Needs Screening Tool, is to quickly identify households at risk for food insecurity, allowing providers to target services and interventions that address the health and developmental consequences of food insecurity.

RDNs working in health care settings, e.g., hospitals, long-term care, residential care, or free-standing dialysis facilities actively address discharge planning needs directly or in collaboration with a social

worker or care coordinator to achieve improved outcomes for patients/clients and the organization, e.g., avoid hospital readmission. In addition to RDNs working in health care settings, RDNs in community nutrition or population health conduct population health management to achieve improved clinical health outcomes of the community/population.

The Academy has created a Practice Tips: Addressing Food and Nutrition Security (https://www.eatrightpro.org/practice/quality-management/competence-case-studies-practice-tips) to help RDNs assist patients/clients with these issues and to improve the health of the community at large.

America's Essential Hospitals

Data is a key driver in health care delivery, informing providers of patient needs while engaging patients in their own care. Hospitals are no longer expected to simply treat a diagnosis and episode but to take responsibility for the overall health and outcomes of their patients. America's Essential Hospitals supports this measure as the first screening measure addressing social determinants of health. We agree with the decision of conditional support for rulemaking pending NQF endorsement and would encourage clear indication in the measure specifications that there is flexibility in the use of screening tools.

Health Hats

The Social Determinants of Health criteria don't include internet access. A major miss.

Carolina Complete Health Network, North Carolina Medical Society

As a cardiologist, health network executive and board member of the North Carolina Medical Society, I'm writing in support of MAP MUC-134 and 136. I serve as the President and Chief Medical Officer of Carolina Complete Health Network. This corporation is a first in kind joint venture between a large national payor, Centene Corporation, and the North Carolina Medical Society. Other investors in the enterprise include the North Carolina Community Health Center Association and individual community health centers serving the most vulnerable patients of North Carolina. This venture partners joined together to identify and address the gaps in healthcare that exist across NC by having the payor and provider work together to eliminate barriers to whole person health.

As the only provider-led entity in Medicaid Transformation in North Carolina, we hope to utilize data around the social drivers of health to create better individual care management support. However, to truly close the gaps in care quality, we need to pool this information and partner with community, municipal and state leaders in a community-based approach. The MAP MUC 136 hospital measure would allow this to be possible.

During my testimony in front of the MAP Hospital workgroup on 12/15/21, I referenced a scenario of high-risk acute myocardial infarction complicated by cardiogenic shock bringing a patient into hospital care. The treatment algorithm for this acute condition branches based on the patient's social drivers of health: having resources will save your life. There is no time to change the support available for the patient. High impact decisions, such as moving toward emergent cardiac transplant or left ventricular assist device use, are made based on social resources available to the patient at the time of the emergency.

Outside of basic clinical criteria, the social drivers of care are the deciding factor in who receives these

supports. The health disparities associated with these heroic interventions, transplant and cardiac assist devices, are designed inside the current system. The care will not change unless we are able to go upstream: to assess the disparities on a longitudinal basis and build and complete an investment map for equity.

This increase in resources that could come from mapping deficits prior to emergency decisions around lifesaving care would generate capacity to turn the tide of health disparities. Patients would receive available treatments knowing that the appropriate social support exists in their hospital and surrounding communities.

While I agree that the hospital reporting might need clarifying score system for consumers (ex: hospital is located in a community at high, moderate or low probability of meeting social needs), it should not paralyze us from taking the needed action. Other reported outcomes that are heavily driven by social factors, for example acute MI, are already being released. Hospitalized patient outcomes are steeped in the social health of the patients in their communities. Let us take the bold step of recognizing and reporting this linkage for a more equitable future in healthcare.

Hennepin Healthcare

I am commenting on as a member of the MAP's Health Equity Advisory Group and the Chief Health Equity Officer for Hennepin Healthcare. I am writing to provide my personal opinion regarding measures MUC21-134 and MUC21-136. These measures directly address CMS Meaningful Measures 2.0's stated measurement gap/priority which focus on the "social and economic determinants." Of the 44 potential Medicare measures under consideration this cycle, only three are tagged to the domain of "equity" – and these two DOH measures are the only patient-level health equity or DOH measures. Addressing health equity at the patient-level is critical in making lasting equity improvements as seen in the MAP Health Equity Advisory Group's positive assessment of these measures, which are publically available for review. I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. As a health system, it is important to be able to have access to these screening measures. I request the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. Hennepin Healthcare has a deep commitment to and experience in addressing patients' SDOH. Our population health department has partnered with community in a multitude of ways to work on SDOH. It is clear to me that that it is important not only to screen for SDOH, but examine and learn from the resulting SDOH screen positive rate data. We can't be afraid to be transparent and honest about where we truly are on the continuum. Hospitals will be able to satisfy the performance threshold by reporting the SDOH screening rate and screen positive rate to CMS. Performance is not determined based on the screen positive rate. Variability in this rate would of course depend on the institution's community context and patient population. Hospitals' reporting the screen positive rate would be important to these institutions and their patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. The objective of this first phase of federal SDOH measures is focused on collecting SDOH baseline data in a standard way to then support a data-driven approach to addressing health-related social needs and inform potential future measures. We cannot allow the perfect to be the enemy of the good in tackling the SDOH, but enable learning and improvement over time. We have to start and fail forward in this work. On this basis, I encourage the MAP Coordinating Committee to enable

CMS's commitment to addressing equity by recommending MUC2021-134 and MUC2021-136 for MIPS and the IQR.

Optum
Patrick Conway, CEO, Care Solutions, Optum

Former Chief Medical Officer, Director of Center for Medicare and Medicaid Innovation, and Principal Deputy Administrator for Centers for Medicare and Medicaid Services (CMS)

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

I applaud CMS for including the first measures specifically focused on the drivers of health (DOH) on the 2021 Measures Under Consideration (MUC) list – and the MAP for its thoughtful consideration of MUC2021-134 and MUC2021-136. These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.

I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. Given the well-recognized impact of DOH health outcomes and cost and, in particular, their disproportionate impact on communities of color, this represents a significant and historic milestone for our healthcare system.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. MUC21-134 (the screen positive rate) is especially important to both practicing physicians (like me) and to our patients given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities.

What really matters to people is that health is more than medical care and that social drivers have outsized impact on health and healthcare costs. It is important to build models that care for people's physical, mental, and social needs, including home- and community-based care. To do so effectively and equitably, it is imperative to collect person-level DOH data– as essential step to improving patient outcomes, both by helping people access the resources they need to be healthy and enabling healthcare institutions to invest in and partner with communities.

Person-level DOH data is essential to quantify the health and economic implications of DOH and inform work on DOH-related billing codes, risk-adjustment, and cost benchmarks. For example, it is well-documented that a diabetic that is food insecure costs, on average, $4,500 more PMPY and has a greater risk of complications. Not knowing if a diabetic is food insecure is both an urgent safety and quality issue and a cost issue that must be understood – as well as key to understand and address health disparities.

I look to CMS to drive learning and accountability on the impact of DOH at the federal level. Inclusion of these DOH measures in regulatory programs like MIPS and the HIQRP would create an unprecedented opportunity to fuel collaboration across public and private partners, address factors that drive inequity in health outcomes, and begin to close CMS's stated measurement gap on the "social and economic determinants."

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Through CMS Innovation Center models such as Accountable Health Communities and Comprehensive Primary Care Plus (CPC+), CMS has amassed years of data and learning across millions of beneficiaries and thousands of practices and clinical sites across the country – demonstrating that implementation of DOH screening can be done reliably and consistently over time. Further, use of these measures has revealed that 34% of beneficiaries screened positive for at least one health-related social need and those who screen positive are disproportionately racial/ethnic minorities.

Building on this foundation – and recognizing that it is untenable to continue to defer collecting and reporting data on those factors that drive up to 80% of health outcomes and associated costs – it is now time for the MAP to recommend that CMS include the first-ever DOH measures in a regulatory program.

Citations:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

IU Health

We would like to ensure that multiple evidence-based screening tools can be used including PRAPARE. Since we do not use the AHC screening tool but PRAPARE instead, we want to ensure that this would be an acceptable format.

American Heart Association

While the type of information collected in this measure would be valuable, this measure may be more appropriate if also reported at system or regional level.

The AHA supports the intent and importance of this measure, but has concerns about the data capture that would be required for this measure as it may not be collected in a hospital's electronic health record and may put additional burden on hospitals to be able to capture this information.

NC Medical Society

As North Carolina's oldest professional organization, including nearly 12,000 members and a network of county medical societies and specialty societies across the state, we note the significance of the MAP's consideration of the first-ever SDOH measures and the only patient-level health equity measures this review cycle.

NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health care providers have been taxed as never before.

With this context, we register our strong endorsement of the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

Further, NCMS further urges the MAP Coordinating Committee to support not only the SDOH screening measure, but also the SDOH screen positive rate measures for the IQR. Representing the perspective of front-line physicians in a diversity of urban and rural practice settings, we recognize that the MAP's

endorsement of both these measures are crucial.

We and others would anticipate significant variability in the SDOH screen positive rate for practices (via MIPS) and hospitals (via IQR) depending on the community context and patient population – and also understand that the measure's value is in spurring physicians and institutions to collect and make visible this data visible.

This data would be invaluable in enabling public and private institutions to make strategic investments to strengthen community capacity to meet patients' health-related social needs, thereby alleviating the challenges faced by patients and the associated burden of these issues on physicians.

Indeed, our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

Finally, it would be deeply demoralizing for practicing physicians to engage their patients around these crucial issues, only to then not have their institutions make the results of this SDOH screening public – reinforcing physicians' longstanding concerns regarding measurement burden that does not translate to value for providers or their patients.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and to laying the foundation to invest in those community resources necessary for health. We urge the MAP Coordinating Committee to evidence its commitment to addressing equity and to addressing the realities of patients' lives and their impact on physicians by recommending to CMS both MUC2021-134 and MUC2021-136 for MIPS and the IQR.

Boston Children's Hospital
Dr. Kathleen Conroy
Public Statement on 2021 CMS Measures Under Consideration:
MUC21-134 and MUC21-136

As a practicing pediatrician and the Clinical Chief of Boston Children's Hospital's primary care center, with deep experience in implementing screening for social determinants of health, I offer my enthusiastic support for the decision of MAP Clinician Workgroup to support both MUC2021-134 and MUC2021-136. Further, I encourage the MAP Coordinating Committee to recommend both these measures for Hospital Inpatient Quality Reporting Program.

At my own practice, which serves 22,000 children, we have been formally and universally screening the adult caregivers of these children for SDOH for over a decade – along with many of our peer institutions across the country. Like many clinicians, we adopted this practice because of the overwhelming evidence that screening is both acceptable to families and helps facilitate connections to needed social resources, like housing programs or SNAP benefits, which themselves are associated with positive

impacts on child and adult health and well-being. Just like screening for depression and anxiety, screening for and addressing social determinants of heath has become a standard part of our clinical program.

More recently, in 2018, the Massachusetts Medicaid program introduced two quality measures through its current 1115 waiver that are nearly identical to MUC21-134 and 136. Although we were already screening, the need to report the percent of our patients screening positive for various needs across our clinic and our entire ACO population allowed us to understand two things: (1) who in our population was most likely to have needs and how these needs are changing over time and (2) whether our systems of screening and response were unintentionally inequitable.

This knowledge has become the foundation for both disparities-focused quality improvement programs and also the impetus for the creation of new community partnerships to be better address needs of certain populations. For this reason, I would argue that both MUC21-134 and 136 are crucial.

To those who may be surprised that these measures do not require navigation to resources, I would offer that Massachusetts similarly did not initially require navigation to resources. This has allowed healthcare organizations the opportunity to build their response systems after initially understanding their families' needs, and it has allowed them time to build data systems to record the social needs responses delivered to families. In my clinic, for example, we recognized that we were under-documenting our work with families once needs were identified and have improved this in anticipation of needing to ultimately report our response to positive screens.

Likewise, it is important that these proposed initial social determinants of measures specify the five target social determinants of health domains (linked to the Accountable Health Communities model), but do not require the use of a specific screening tool, enabling providers to exercise flexibility in this regard.

Given my own extensive, on-the-ground experience functionally implementing these specific SDOH measures – and recognizing that it is untenable for our healthcare system to continue to defer collecting and reporting data on food insecurity, housing instability, and other social factors that drive up to 80% of health outcomes and associated costs – I strongly recommend that the Coordinating Committee recommend MUC21-134 and 136 to CMS for implementation in MIPS and the HIQRP.

Texas Medical Association

TEXAS MEDICAL ASSOCIATION 401 WEST 15TH STREET AUSTIN, TEXAS 78701-1680 (512)370-1300 FAX (512)370-1693 WWW.TEXMED.ORG
January 13, 2022
The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Ave.
Washington, DC 20201
RE: Texas physicians continue strong support for measures that drive health quality (MUC2021-134 and MUC2021-136)
Dear Administrator Brooks-LaSure:

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On behalf of our more than 56,000 Texas physician and medical student members, the Texas Medical Association (TMA) writes with our further support for measures that drive health quality. In addition, we continue to support the National Quality Forum's Measure Applications Partnership (MAP) process.
At TMA, we recognize that social determinants of health (SDOH) have a profound impact on patients and the physicians who care for them, especially in the wake of COVID-19. The two measures MUC2021-134 and MUC2021-136 signal that the Centers for Medicare & Medicaid Services (CMS) has begun to recognize and address the significant impact that social determinants of health have on health disparities, outcomes, and costs. Additionally, social drivers impact both physician well-being and the economics of clinical practice.

With this context, we register our strong endorsement and support of the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

TMA strongly urges the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital Inpatient Quality Reporting Program (HIQRP) – recognizing that both these measures are crucial.

It is crucial to note that, in the absence of any standard SDOH measures, physicians are functionally held clinically and financially responsible because patients with greater social risk – which is not currently measured or included in risk-adjusted cost benchmarks for alternative payment models – are associated with higher health care costs. Obscuring the results of the social needs screening – by rejecting MUC21-136 –would make invisible crucial drivers of health outcomes, costs, and disparities, and impede appropriate investments in the community resources necessary to improve our patients' health.
For example, via the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities model – which extensively tested these specific proposed SDOH measures in more than one million beneficiaries in both hospital inpatient and emergency department settings and primary care practices– CMS learned that 34% of beneficiaries screened positive for a health-related social need, and among that group, racial and ethnic minorities were over-represented. Further, it identified that food insecurity was the most commonly reported health-related social need among navigation-eligible beneficiaries, followed by housing and transportation. It is this kind of data that is imperative to understand the needs of patients and communities, as well as the underlying factors driving variation in health care costs. For example, numerous studies have now quantified the impact of patients' social risk on physician performance scores through the Merit-Based Incentive Payment System (MIPS) and its impact on the geographic variation in Medicare spending (37.7% when including both direct and indirect associations).

Recognizing this, physicians in Texas already are working to effectively identify and address their patients' health-related social needs. We do so recognizing that screening patients for social determinants of health is, as one of our colleagues recently observed, "just like when you use a screening tool or test to diagnose a medical condition. The diagnosis and the plan to address the problem can be enhanced by understanding some of the social needs, i.e., social determinants, that can get in the way, or may have already gotten in the way of making this person as healthy as they could be. This is not about ascribing fault as much as it is identifying factors that should be considered or addressed."

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TMA strongly supports that the MAP Coordinating Committee recommend both MUC21-134 and MUC21- 136 for both MIPS and HIQRP, recognizing that doing is essential to advance CMS' stated commitment to equity as well as to enacting measures that matter to patients and physicians. We appreciate the opportunity to comment on this matter. If you have any questions, please do not hesitate to contact Karen Batory, MPA, TMA vice president of population health and medical education, at Karen.Batory@texmed.org.
Sincerely,
E. Linda Villarreal, MD
President
Texas Medical Association

Humana, Inc.
January 13, 2022

National Quality Forum
Measure Application Partnership
1099 14th St. NW, Suite 500
Washington, DC 20005

RE: 2021-2022 Recommendations for Measures Under Consideration

To Whom It May Concern:

This letter is in response to the National Quality Forum's Measure Application Partnership (MAP) comment opportunity on the 2021-2022 Recommendations for Measures Under Consideration. Humana applauds CMS for including the first measures focused on the social drivers of health (SDOH) on the Measures Under Consideration list, MUC21-134 and MUC21-136. These SDOH measures directly address the Centers for Medicare and Medicaid Services (CMS) Meaningful Measures 2.0's stated measurement gap/priority focused on the "social and economic determinants."

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 4.4 million members and Medicare Prescription Drug Plans (PDPs) with approximately 3.9 million members, we are distinguished by our nearly 35-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the Medicare Advantage program as their safety net and many in underserved areas – receive integrated, coordinated, quality, and affordable care through our plans.

MUC21-134 and MUC21-136

In COVID-19's wake, food insecurity, housing instability, and other SDOH have reached unprecedented levels and revealed massive racial disparities. Yet, despite the well-documented impact of SDOH on health outcomes and costs and their disproportionate impact on communities of color, there are still no SDOH measures in the Quality Payment Program (or other CMS quality and payment programs), which is only more significant in light of COVID and HHS/CMS's commitment to equity.

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We recognize that of the 44 potential Medicare measures under consideration by CMS this cycle, only three are tagged to the domain of "equity," including these two measures. We also note the MAP Health Equity Advisory Group's positive assessment of these measures.

With this context, we write to endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 for inclusion in the Merit-based Incentive Payment System (MIPS) and encourage the MAP Coordinating Committee to accept this decision. We believe this is a historic milestone for our healthcare system.

Humana further strongly urges the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital Inpatient Quality Reporting Program (HIQRP). We believe it is important to include both measures because, together, they will make visible the impact of health-related social needs on patients.

MUC21-134 (the screen positive rate) is especially important in that it creates the opportunity to reveal and address disparities, both with respect to SDOH and their impact on health outcomes and costs. This anticipated variability in screen positive rates – including SDOH disproportionate impact on diverse communities and communities of color – would be important in enabling public and private institutions to direct investments in communities.

From Humana's perspective, we have long been committed to addressing the impact of health-related social needs on our members and addressing SDOH in communities across the country. In 2020 alone, we completed 6.2 million SDOH screenings; this data and the overall SDOH screen positive rates of our members, which we have made public, has been invaluable in enabling us to partner effectively with dozens of other organizations in addressing needs among our members and in communities, including appropriately targeting our investments to address these issues.

While we agree that taking action on the result of the screening is important – and is something Humana itself is committed to doing – we recognize that the objective of this first phase of federal SDOH measures is focused on collecting standardized SDOH baseline data to support a data-driven approach to addressing these health-related social needs and inform potential future measures. In this regard, we believe – and have learned through our experience at Humana – that we cannot allow the perfect to be the enemy of the good in tackling the SDOH, but instead must prioritize learning and improvement over time.

On this basis, we encourage the MAP Coordinating Committee to enable CMS's commitment to addressing equity by recommending MUC2021-134 and MUC2021-136 for MIPS and the HIQRP.

We value this opportunity to provide comments and are pleased to answer any questions you may have. We hope that you consider our comments as constructive feedback aimed at ensuring that we continue to advance our shared goals of improving the delivery of coverage and services to Medicare beneficiaries and addressing health disparities, focused on improving the total health care experience of all Medicare beneficiaries.

Sincerely,
J. Nwando Olayiwola, MD, MPH, FAAFP

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Chief Health Equity Officer & Senior Vice President
Humana, Inc.

Andrew Renda, MD, MPH
VP | Bold Goal & Population Health Strategy
Humana, Inc.

Johnson & Johnson

Johnson & Johnson agrees with the recommendation of the Workgroup of conditional support. It is important to routinely screen patients for social drivers of health that may impact access to diagnostics, treatment, and supportive care services. We appreciate the flexibility the measure offers for screening approaches but support future standardization of tools to ensure that providers have clear guidance and best practices for identifying patients at risk. While clinician and practice-level screening is important, it will not capture patients whose social drivers prevent them from accessing care entirely. Transportation, health literacy, education, and living situation, among other factors, significantly impair individuals from accessing care in the first place. We therefore encourage CMS and NQF to think about measures at other levels of analysis (e.g., surveillance measures) to understand how these social drivers impact Medicare populations more broadly.

Cambridge Health Alliance

As a family medicine physician practicing at the Cambridge Health Alliance in Cambridge, Massachusetts, I applaud CMS for considering the first measures specifically focused on the social drivers of health (MUC2021-134 and MUC2021-136) and the NQF MAP for its consideration of these measures.
These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.
For the past decade, I have been deeply involved in efforts by CHA and other health systems and community health centers in MA to screen patients for the social drivers of health. I have extensive experience implementing SDOH screening and navigation protocols at scale and have published on the resulting findings.

It is clear that food insecurity, for example, is not just a social factor, but a clinical co-morbidity that impacts quality care and drives health disparities.
Given COVID, SDOH screening has become only more critical to support our patients and to mitigate the frustration and burnout among primary care providers. Yet, we now do so without the benefit of any SDOH measures in any federal payment program, including MIPS. It is untenable for our federal payment programs to continue to exclude those factors that we know drive 80% of health outcomes in our patient populations.

At CHA, my colleagues and I have screened thousands of patients in over a dozen primary care sites across our healthcare system; in doing so, we found that nearly 30% of our patients screen positive for food insecurity.

Had we not collected and share this data, we could not have developed effective strategies and community partnerships to address these challenges with our patients. In particular, this crucial data about our patient population – exactly the kind of foundational data that these SDOH measures will provide – then allowed us to design an electronic active referral to a community-based organization.

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One question that has come up is whether these measures will, hypothetically, incentivize providers to treat fewer patients with social needs or to move way and care wealthier patients. But from the perspective of a physician who – like thousands of others across the country – is committed to serving patient populations that often face these challenges, these first-ever federal SDOH measures are essential to recognize practices (like mine) that are tackling these issues.

With this, I enthusiastically support the MAP Clinician Workgroup's decision to recommend both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. The latter measure is especially important to practicing physicians and to our patients, given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities, as we have done at CHA.

Intermountain Healthcare

Intermountain Healthcare agrees with MAP that this measure, while potentially very valuable for improving patient experience of care and health in the community, is not ready for further rulemaking at this time.

Hogg Foundation for Mental Health

This is an important measure to consider to finally start including the impact of the social determinants in the ambulatory setting. The data generated will provide greater understanding and lead to more informed interventions by the clinical team and for social interventions. Extremely important for interdisciplinary team-based care. The benefits do outweigh the cost of data collection, especially when one considers this measures potential to track and monitor the quality of holistic health care outcomes. The challenge will be for all providers and team members to include and utilize this measure appropriately.

The Physicians Foundation

We also urge the Coordinating Committee to accept the Hospital Workgroup's recommendation to offer conditional support to MUC21-134. We likewise recognize that Workgroup's questions regarding how CMS and consumers could or should interpret the screen positive rate results required by MUC21-136.

As CMS itself made clear in this discussion, hospitals would satisfy the performance threshold by reporting the screening rate and screen positive rate to CMS for patients who are 18 years or older at the time of admission. Performance is not determined based on the result of the screen positive rate; there is no requirement to demonstrate a rate reduction over time. Variability in this rate would, of course, depend on the institution's community context and patient population.
Hospitals' reporting of the SDOH screen positive rate is valuable to consumers for a number of reasons, including (1) providing transparency of data the institution has collected from those and other consumers who received care at the institution; (2) enabling public and private institutions – including the hospitals themselves – to target community investments based on data consumers provided; (3) allowing consumers to identify which hospitals have familiarity with and expertise in addressing these issues; and (4) enabling quality improvement activities, including making visible variation in health

outcomes and costs potentially attributable to the prevalence of these underlying drivers of health and addressing disparities.

We agree that it is important to bridge patients who screen positive for health-related social needs to community navigation services and/or ensure there is an individualized action plan in place for these needs to be addressed. However, physicians are well aware that this is complex and resource-intensive work, which is dependent on the quality of the community resource landscape where their practices and/or health systems are located and their patients live. Hence, the objective of this first phase is focused on collecting DOH baseline data in a standard way to then support a data-driven approach to addressing these health-related social needs, including potential future measures focused on success in navigating patients to the resources they need to be healthy. To establish an SDOH navigation measure in the absence of practices and hospitals reporting baseline SDOH screening data is inadvisable.

Moreover, it must also be stressed that the validation of any screening tool used to collect data supporting a measure must include the result of the screen. Should the Coordinating Committee recommend the screening rate measure but reject the screen positive rate measure, it will impair the ability of CMS, the measure steward, and program participants to conduct additional validation of the screening rate measure post-implementation and over time.

We expect, and hope that, over time, these SDOH measures can and will be improved – and additional associated measures developed – with the benefit of the input of physicians, other healthcare providers, and health systems across the country and the data generated by these measures.

We also recognize, however, that given the profound challenges that COVID has wreaked on patients, physicians, and our healthcare system writ large – and the commitment to equity and the reduction in health disparities that CMS and healthcare institutions across the country have declared – that time is of the essence in enacting these first-ever SDOH measures (and the only patient-level equity or SDOH measures under review this cycle). We therefore strongly urge that the Coordinating Committee recommend to CMS MUC21-134 and MUC21-136 for both MIPS and the IQR.

Citation: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/

Vizient, Inc.

We comment NQF and CMS for efforts to prioritize health equity, including the development of a measure to capture screening of social drivers of health for patients. Vizient, Inc. is the nation's largest health care performance improvement company and serves a diverse membership of hospitals and other non-acute health care service providers in rural America, including independent community hospitals, critical access hospitals, rural health clinics and other non-acute providers. Vizient and its members recognize the critical need to addressing social drivers of health for each patient to ensure equitable health outcomes for all patients in our community, and wholly support efforts to increase screening all patients for social drivers of health.

Our concerns with MUC2021-136 include the lack of definition for "screening" and "social drivers of health" as related to this measure. Clear and consistent definitions are critical to collecting data that can be meaningfully used by the health care system to improve outcomes for patients. In addition, defining such terms also supports identification and use of validated screening tools. Without consistency, it will be difficult for health systems or CMS to address the patient needs and risks identified during the

screen, and potentially harm patients by impairing their ability to efficiently access needed services, creating confusion if communication between health systems is inconsistent and eroding trust when their needs are recorded inconsistently. We would recommend this measure under certain condition, particularly that CMS defines these terms clearly prior to approving this measure.

In addition, Vizient is concerned that finalizing this measure before there is a standard approach for collecting screening data related to social drivers of health will limit the utility and comparability of collected data. Standardization is critical for ensuring that patient data collected by health systems can be effectively utilized to address community needs and ensure that future measures promote community-wide improvements in social drivers of health. A risk of approving this measure without standards is that inconsistent data collection will yield incomplete or unusable data sets, which could make any future analysis for development of new measures to addressing social drivers difficult. We encourage NQF and CMS to work with stakeholders to define and set the standard for data collection to ensure the patient data collected will be used to promote health equity.

Association of American Medical Colleges (AAMC)

The AAMC agrees with the MAP's recommendation. The AAMC fully supports efforts to screen patients for their health-related social needs and agrees that a quality measure consistent with guidelines could help improve and standardize screenings. That said, we believe this measure should be NQF endorsed prior to use in the IQR Program to ensure that the measure is valid and reliable. During the MAP Hospital Workgroup there was significant discussion regarding confusion as to the denominator for this measure, and whether it would require a patient to be screened at certain intervals or at every interaction with the hospital regardless of how frequent. One suggestion is that the measure developers consider including a reasonable interval for screening - potentially every six months, if supported by the literature. Furthermore, there was some discussion around appropriateness of excluding incapacitated and/or trauma patients who may not be able to be screened at admission. The AAMC is concerned about the suggestion from the measure developer that patient's family members or caregivers could complete the screening on the patient's behalf in such cases due to the sensitivity of screened needs, notably interpersonal safety. We believe the NQF endorsement process is vital to ensuring this measure is appropriate for use in the IQR Program.

Kaiser Permanente (retired)' NASEM Roundtable on Population Health Improvement (co-chair); Secretary, CDC Foundation Board of Directors; Trustee, Blue Shield of CA Foundation

We know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health. Some have suggested it is not feasible to do this at scale in the clinical setting. Two decades of work by Kaiser Permanente has demonstrated that this is not only feasible and effective, but embraced by clinicians and patients when the right tools and processes are put in place. Kaiser Permanente built its SDOH screening and followup on a clinical prevention platform that had already included, for example, screening for tobacco use, physical activity and domestic violence. As Kaiser Permanente's extensive community health investments deepened its understanding of how factors like food and housing security and personal safety shaped the health of individuals and entire communities, the system introduced more formal screening, referral and community partnerships to realize the full potential of identifying and addressing SDOH.

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Now, many healthcare delivery systems across the country have committed to screen and address their patients' social needs – but are doing so without the benefit of any SDOH measures in any federal payment model, including Medicare or Medicaid. Indeed, a recent study in JAMA found that 24% of hospitals are already screening for all 5 SDOH domains (food, housing, transportation, utilities, and interpersonal safety) and 92% are screening for one or more of the 5 SDOH domains specified in the measures. At the same, a 2020 study conducted at Kaiser Permanente found that patients were in favor of health systems asking about social needs (85%) and helping to address those needs (88%).

With this context, I write to offer my support for the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.
I further urge the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital IQR, recognizing that, together, these measures reveal the impact of health-related social needs on patients and the opportunities to realign resources to invest where they are needed most.
It is important to note that both the SDOH measures under review today are critical to make visible the impact of these issues on the lives of patients and the disparities they spur. Given the disproportionate impact of SDOH on people of color, equity requires us to recognize providers for screening their patients and reporting the screen positive rate, to elucidate racial/ethnic disparities in DOH that, in turn, fuel disparities in health outcomes.
One key lesson we've learned in this work over the past twenty years is that we cannot allow the perfect to be the enemy of the good. The MAP Coordinating Committee has a crucial opportunity to support moving the first-ever SDOH measures into practice to enable learning and improvement over time. The data collected and learning from these foundational SDOH measures will be critical to improve the measures over time and to be thoughtful in developing the next set of measures focused on ensuring patients get the resources they need.
Finally, we are cognizant that there only 3 measures tagged to the domain of "equity" and these are the only patient-level SDOH measures or equity measures under review, making it all the more imperative that the MAP Coordinating Committee recommend them. In the wake of COVID, it is simply unacceptable to go yet another year without any federal payment program measures that recognize the profound impact of SDOH on the lives of our patients.
Citation: https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2751390
https://pubmed.ncbi.nlm.nih.gov/31898132/

American Hospital Association

In step with our comments regarding the Hospital Commitment to Equity measure, the AHA believes that this measure addresses a critical gap in care but is not sufficiently specified and tested for use in measuring hospital care hospitals to merit conditional support from the MAP. Instead, we recommend that the measure steward refine and further test this measure—not merely the screening tool upon which the measure is based—to determine whether it has potential to improve outcomes. While screening for social drivers of health is an important way to gather patient-level information, the measure as currently specified lacks several important details about how the information would be interpreted and used. Without further clarity and data to demonstrate that this measure gleans useful and actionable information, the measure is not suitable for inclusion in CMS programs.

The measure has only been tested for construct validity—that is, the measure steward has analyzed the psychometric properties of the Accountable Health Communities Health-related Social Needs tool that includes questions addressing topics in the measure's description. The measure itself has not been

tested; it has been trialed in certain settings, but as best we can tell, no reliability or validity testing has occurred to show that the measure is feasible in an inpatient (as opposed to primary care) setting. In addition, the measure apparently does not require the use of this particular screening tool; at the MAP meeting, the steward and CMS noted that any tool used would have to "mirror" certain questions that appear in the ACH tool, and "in the future" CMS could mandate the use of a specific set of tools. It is clear from the short history of this measure that it has not been sufficiently investigated.

Adding further complications is the lack of clarity around the applicable patient population in the measure's denominator. In the measure's description, the denominator is listed as the "number of beneficiaries 18 and older in the practice (or population)." This is far too vague to be usable in an inpatient context. When asked to clarify during the MAP meeting, the measure steward explained that "ideally" inpatient providers would be performing "universal screening upon admission," and that the "focus is on Medicare beneficiaries." Neither of these responses provides a usable definition of the measure's denominator. We hope that the steward can answer the following questions to specifically define the population included in this measure: Is the denominator limited to new patients, or all patients, or all members of the community? How frequently do individual patients need to be screened to be counted in the denominator, and does each screen enter into the quarterly rate (or just each patient who has been screened)? Who will perform the screening, and at what point in the encounter?

Several additional details are missing. First, there is little information about how this data would be reported. The steward noted that the "information comes from chart abstraction or an EHR, like a census," but there is no information suggesting that the information included in this measure is available in medical records in standard formats. The AHA recognizes and supports the importance of collecting data on social drivers of health in consistent and precise ways; this measure as currently designed would at best fail to achieve that goal and more likely move farther away from it due to its lack of specificity.

Finally, this measure suffers from a major conceptual issue in that it lacks evidence linking use of the measure to beneficial effects on patient outcomes. To be clear, we agree with the concept that performing screenings and collecting data on non-medical needs is important for hospitals to do, and have been working with hospitals to encourage them to do so. Yet, the question before the MAP whether the specific approach prescribed in this measure – which would be required of all hospitals – is best suited to the task of improving outcomes. Like identifying cancer or disease, identifying a social need is only a first step and the identification of the problem does not alone result in better health. Applying this measure to inpatient hospitals stretches the boundaries of what providers can feasibly address; is it truly an indicator of the quality of clinical care provided that a hospital performs screenings but members of its community still experience housing instability or interpersonal danger? Without evidence that connects performance on this measure to better patient outcomes, it is hard to assess whether its implementation would lead to the improvement in outcomes that CMS hopes.

Finally, notwithstanding whether this measure is implemented, it is important to note that hospitals and health systems are already working to improve the health of their communities, and are using approaches like by conducting community health needs assessments to identify and develop strategic plans to to address the unique characteristics of individual communities. While these tools are robust, hospitals are committed to doing even more to ensure the care they deliver is equitable.

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Camden Coalition of Healthcare Providers

The benefits of the measure will not necessarily outweigh the burden of data collection or reporting. This will depend on many practice-level factors, such as the ability to develop efficient screening workflows, the availability of staff who are trained and well-prepared to engage patients with complex social needs (especially around sensitive needs such as those related to interpersonal safety), the smooth integration of screening data into a practice's existing data systems, and the ease with which the data can be made available to clinicians at the point-of-care. Moreover, the interpersonal safety questions are proprietary, and from a practice's perspective, it may not be worth the cost of including those questions in their screener, especially if there are inadequate resources available to address any interpersonal safety issues a person is experiencing. We would recommend offering alternative questions related to interpersonal safety for practices who do not want to pay to use the four questions currently included in the AHC screener. Finally, with reimbursement, benefits may outweigh burden as long as practices are given flexibility in how social needs screening takes place and the reporting requirements are not cumbersome.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

The Camden Coalition is an Accountable Health Communities alignment track hub. The social needs screening data we collect are used for multiple purposes locally and regionally. For example, we share the data with health systems and other community partners for community health needs assessments and gaps analysis; we leverage the data to procure funding for various population health initiatives; we make the data available through our Health Information Exchange to inform clinical decision-making; and we share the data with researchers who study the intersection of social risk and health.

Are there implementation challenges?
Challenges include incorporating the screening tool into practice workflows, throughput, cost, potential need for extra staffing, and storing and accessing the data. If the screener is self-administered, challenges related to staffing might be reduced, but there are other challenges that need to be considered. An efficient workflow still needs to be established - for example, determining when during a visit a patient will receive the screener and who on staff will be responsible for introducing the screener to the patient. Language and literacy barriers present challenges as well and may require additional time and support from staff. Additionally, if a practice is doing more than collecting data and is going to establish workflows to respond to social needs, there are coordination costs associated with addressing those needs. There would need to be people on staff who can have the kinds of conversations that must take place when a patient expresses a social need. This may mean hiring a social worker, for example, or taking on the cost of training existing staff members.

KAREN L SMITH MD PA

All patient access points are necessary to participate in the screening process in order to capture the best data.
Patients without a medical home often utilize tertiary care centers and this is a opportunity to obtain information which can impact regional care
Hospital exclusion from this activity is a missed opportunity

Carolina Complete Health

The work of several CMS Innovation Center models like Accountable Health Communities, Comprehensive Primary Care Plus and others has demonstrated that screening for and acting upon

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these drivers of health is impactful for millions of Medicare and Medicaid beneficiaries, both in inpatient and outpatient settings. However, because this work has been done without the availability of standard SDOH measures or screening tools, CMS cannot systematically compare or use that wealth of data in a reliable fashion. The promise shown by these innovative efforts should not be minimized given the immense opportunity we have to improve overall outcomes and have meaningful impact on disparities amongst us. It should be encouraging to all that these proposed measures have been effectively implemented in AHC over 5 years now and across >1M CMS beneficiaries in 600 clinical sites and multiple practice settings across the country. It also should be reassuring that the AHC screening tool has been objectively shown to be reliable with concurrent and predictive validity.

The ideal convention would be use of the Social Driver of Health Screen Rate measure and the SDOH Screen Positive Rate measure in tandem. Given the disproportionate impact of SDOH on people of color, these measures account for actual screening that occurs but also recognizes providers for reporting the screen positive rate for their patients. Given the variability in the prevalence of SDOH across geographies and patient populations – as well as in clinical sites' capacity to provide patient navigation – the suggested approach for introducing such measures into the federal quality frameworks is critical.

While it is understandable that some entities may perceive being negatively and/or inappropriately burdened by sharing such data publicly, representing circumstances not fully under the entity's control, the reality is that many physicians and other health care entities serving in underserved settings have had to be compared against more ideally situated colleagues with the same quality measures despite caring for individuals who bore these often recognized but rarely addressed barriers to optimal outcomes. I experienced that directly in pediatric practice in East Winston-Salem, NC and in SE Washington, DC. So I strongly believe that implementation of these measures can increase the capacity of our systems to recognize needs, foster innovative support and more efficiently utilize available resources. Screening without sharing the results for action portends a risk that some might turn a blind eye and that others might just choose to move to more favorable settings. Allowing a true and transparent assessment of the populations served, the resources given and the actions that may be undertaken, gives us more global and reliable opportunities to truly shed light on and reverse the impacts of social inequities, deprived communities and even systemic racism. It is on this basis that I submit these public comments.

Respectfully Submitted on January 13, 2022,

William W. Lawrence Jr. MD, FAAP

Huntersville, NC

Wholesome Wave on behalf of the National Produce Prescription Collaborative
National Produce Prescription Collaborative

January 13, 2022

To: Members of the NQF: Measure Applications Partnership

From: Members of the National Produce Prescription Collaborative (NPPC)

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RE: Support for Driver of Health Screening Rate (MUC2021-136) and Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write additional comments in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the "Drivers of Health Screening Rate" and the "Drivers of Health Screening Positive" measures as part of the 2021 CMS MUC list.

We greatly appreciated the MAP Workgroup's strong support for the SDOH measures for MIPS. We ask that as the map process enters its final Coordinating Committee review on January 19, that the Coordinating Committee additional recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its "measures under consideration" list. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through our federal health programs.

Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people's diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long-standing burden of diet-related chronic disease. Unfortunately, these diet- related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

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National Produce Prescription Collaborative

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While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

Applying these measures to both the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — would go a long way to improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) implementing produce prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs

The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country.

A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers. Having DOH measures available to screen for food insecurity will help these government-sponsored health plan practitioners deliver on the growing promise of food as medicine. For example: In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity.

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National Produce Prescription Collaborative

Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercised regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020.

Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare, and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward for consideration.

About NPPC

The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and who are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

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AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. AHIP agree with the initial recommendation to conditionally support the Screening for Social Drivers of Health measure for both IQR and MIPS. AHIP believes that performance measurement is an underutilized tool to address healthcare disparities and supports the advancement of measure of health equity. Given the impact of social determinants of health on a person's health outcomes, screening for social risk factors in an important first step in promoting health equity and eliminating health disparities. We agree that screening for health needs can help providers connect patients to social services.

We suggest that CMS work with the measure steward to refine this measure to include specific screening tools or provide implementation guidance on which screening tools should be used to promote consistency in screening for social determinants across the healthcare sector. Additionally, we recommend that CMS and the measure steward work to ensure alignment with accepted data standards for SDOH. We would recommend that CMS and the measure steward look to the work of the Gravity Project to identify data standards. Ensuring consistency in the screening tools used and utilizing the work of the Gravity Project would align with work health care providers, electronic medical records companies, RHIOs, health insurance providers and government agencies are doing to address SDOH and could promote measure alignment across public and private payers.

University of Chicago, Section of General Internal Medicine

1. How would adding this measure add value? How would the measure improve patient outcomes?

As the National Program Office team at the University of Chicago we work with eight grantee organizations from the Merck Foundation funded Bridging the Gap: Reducing Disparities in Diabetes Care initiative. These organizations are transforming primary care through integrated medical and social care to improve diabetes care and outcomes. We have a national lens on integrated medical and social care activities to support chronic disease care. The initiative transforms primary care through the implementation of integrated strategies to address SDOH, with evolving payment models to support these transformations.

The measures (MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021- 134 (Screening for Social Drivers of Health)) add value by providing an opportunity to change how and what we measure in health care. The opportunity to measure drivers of health (DoH) allows health care teams to have data to identify and address unmet needs and policymakers and payers to account for DoH in health care delivery and financing models. For example, grantees in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have utilized DoH screening at two levels: to understand individual patient needs and to assess the needs across their population. Health care teams have utilized screening to assist with resource allocation and to tailor care for individual patients. At the population level, grantees have harnessed this high-level to better inform the support services needed and to establish critical cross-sector partnerships.

These measures have the potential to improve patient outcomes by establishing approved, standardized DoH measures in Centers for Medicare and Medicaid Services' (CMS) programs. Standardized collection of DoH measures would allow CMS to systematically compare or use the data. DoH measures can provide insight into the social factors that facilitate or constrain optimal health, particularly for vulnerable populations (e.g., older adults, communities of color). Assessing these factors in a standardized way is an important first step towards improving equitable health outcomes.

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2. Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of these DoH measures outweigh the burden of data collection or reporting. These measures are well tested, including through the Accountable Health Communities model, which screened nearly a million beneficiaries for SDOH in over 600 clinical practices.

3. For what purpose are you using the measure (e.g., QI, certification/recognition,regulatory/accreditation, payment, public reporting, disease surveillance)?

The National Program Office at the University of Chicago has utilized positive DoH screening results to better understand the scope of social needs amongst the study population within our initiative, especially among medically high-risk populations. Grantees within the initiative utilize different screening tools and the standardization of DoH screening data has proved to be an area of difficulty in the evaluation process.

4. Are there implementation challenges?

To address implementation challenges it is imperative to plan for documentation of these measures during data collection and options for data extraction. Technical assistance may be needed to support best practices for data collection workflows and data extraction. In addition, providers in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have highlighted that screening for DoH should not be conducted without an appropriate pathway to address the needs screened for. As part of the implementation of screening for DoH, CMS and its partners should consider developing technical assistance to ensure best practices for DoH referrals.

OCHIN, Inc.

These measures are essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes—and this is equally true whether patients are receiving care in ambulatory or in-patient settings. These measures create incentives for the clinical team to identify structural barriers to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care.

Clinicians and providers cannot address social determinants of health if this information is not collected and acted upon. Our nation's health care delivery models must embed incentives—such as quality measures--to improve care for patients facing the greatest barriers to health care and other structural inequities. The need does not change based on site of care since the patient faces the same social risks.

OCHIN is a nonprofit health information technology innovation and research network that serves over 1,000 community health care sites with 21,000 providers in 47 states serving nearly 6 million patients. The OCHIN network provides a continuous learning health system collaborative and offers technology solutions, informatics, evidence-based research, and policy insights. For two decades, OCHIN has advanced equitable health care solutions by leveraging the strength of our network's unique data set and the practical experience of our members to drive technology innovation at scale for patients and providers in underserved communities. To that end, OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting where flexibility is

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provided to optimize workflow and staffing needed to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

We offered in our initial round of comments, as we do here, conditional support for these measures. OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, notes that while that 1 in 4 women experiences IPV in her lifetime, disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN network members' patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, OCHIN recommends not including IPV in the current measures. OCHIN would, however, support a separate measure for IPV focused on the provision of universal patient education.

OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to begin with the domains of housing, food insecurity, and transportation as "core" domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at University of California (San Francisco) that finds these four domains (housing, food insecurity, transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, these are the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations or added as more evidence about the relationship between SDOH and health becomes available.

Blue Shield of California Foundation

Blue Shield of California Foundation strongly supports MUC21-136, Screening for Social Drivers of Health, and MUC21-134, Screen Positive Rate for Social Drivers of Health, and urges the MAP Coordinating Committee to support both measures for rulemaking and inclusion in both MIPS and the Hospital IQR.

Nearly 90 percent of hospitals and health systems across the country are already conducting Driver of Health (DoH) screening to identify patients' unmet social needs, according to one recent study, including via a number of CMMI models, but without the benefit of any formal quality measures, guidance, or tools from CMS.

As evidenced in the momentum for these measures across the health sector, it is imperative that we

begin to implement DoH measures into federal payment programs, especially in the wake of the deep health inequities revealed by our response to COVID. With this context, we applaud the MAP for its thoughtful deliberations on MUC21-134 and MUC21-136, two of only three equity measures under consideration by the MAP and CMS this year.

In particular, we applaud the leadership of the MAP Clinician Workgroup in supporting both MUC21-134 and MUC21-136, and applaud the Hospital Workgroup in likewise supporting MUC21-136 – and encourage the MAP Coordinating Committee to endorse these decisions. We are troubled, however, by the MAP Hospital Workgroup's vote on MUC21-134: "do not support with potential for mitigation."

First, the NQF MAP summary of the Workgroup's recommendation states that the "measure has not been evaluated for reliability or validity." Yet NQF's own preliminary analysis cites documentation that the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of reliability and validity.

Second, the Hospital Workgroup "expressed concern that the positive rate may be challenging for consumers to interpret when publicly reported." Through the lens of a commitment to equity, we find it remarkable that the Workgroup has determined that consumers would be unable to exercise their own judgment in interpreting important data about the degree to which their fellow consumers are impacted by social drivers of health. We believe a hospital's reporting of the screen positive rate will be important to patients for a number of reasons, including: (1) providing transparency; (2) enabling the targeting of hospital and community investments based on the social needs shown by the data; (3) signifying the hospital's understanding of the social drivers of health among its patient population; and (4) providing data for targeting quality improvement activities, including highlighting and addressing disparities in the social drivers of health for patients.

Finally, we recognize that the measures are focused on screening beneficiaries for drivers of health, and do not require an action plan. At the same time, we believe these measures represent an important starting point for collecting DoH baseline data in a standard way to then support a data-driven approach to addressing these social drivers. We note that CMS's own CPC+ model demonstrates clinicians' appetite to engage in this screening and act on these results, even when not required: 86 percent of Track 1 practices reported that they screened patients for health-related social needs (though not required to do so) and 93 percent of physicians in those practices reported that they acted on those screening results.

The introduction of these first DoH measures into core federal payment programs would be significant in its own right: making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all. To achieve this goal, we strongly encourage the MAP Coordinating Committee to recommend to CMS MUC2021-134 and MUC2021-136 for both MIPS and the IQR.

American Medical Association

While the American Medical Association (AMA) supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we continue to have concerns

that this process measure will not lead to improved patient outcomes in the absence of any resources or tools that would be widely and readily available to hospitals. In addition, this measure does not appear to be completely specified or tested. It must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). Because we do not believe that this measure will result in effective change and should be fully specified and demonstrated to be evidence-based, reliable, and valid prior to MAP consideration, we request that the highest level of MAP recommendation be "Do Not Support With Potential For Mitigation."

Unite Us/NowPow, a wholly owned subsidiary of Unite Us

Overall, Unite Us supports including measures 134 and 136 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. We are pleased to see that the Measure Applications Partnership (MAP) Clinician and Hospital Workgroups conditionally approved both measures for MIPs and 136 for IQR. We recommend that the MAP Workgroups also approve measure 134 for IQR.

We understand that a barrier to approval of measure 134 by the Hospital Workgroup was the concern of some members that public disclosure of rates of food insecurity and other health-related social and economic needs could negatively impact a hospital's business. Importantly, thousands of hospitals already publicly reporting these kinds of data through their Community Health Needs Assessments. These assessments commonly include rates of health-related socioeconomic conditions including food insecurity, unemployment, housing instability, transportation needs and poverty. Given the ubiquity of these conditions, it is unlikely that members of the public could or would meaningfully use publicly reported data on prevalent health-related socioeconomic conditions to decide whether or not to elect care at a given hospital or medical center.

In addition, hospitals play a critical role as both anchor institutions and data engines for communities. Public sharing of data about socioeconomic needs of people living in the primary service area enables data-driven community investments by hospitals and others and offers the opportunity to evaluate the impact of community investments on outcomes of shared importance to healthcare and community leaders. Transparently sharing social needs data empowers leaders to confront hard facts, develop targeted solutions to address unmet needs, and forge partnerships between healthcare, communities, philanthropy and government to improve health and well being.

We also note the measure does not require follow-up after needs have been identified. We recommend the creation of additional measures in the future that evaluate whether services to address social needs are provided in a timely manner. Assessing needs without addressing them will not improve quality. Despite these concerns, we believe the measure is a positive first step towards considering and tracking social drivers of health. Including these measures will encourage clinicians and staff to screen and track social drivers of health.

Health Care Without Harm

January 11, 2022

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

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MUC 2021-136; Driver of Health Screening Rate, and

MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post (November 30, 2021) :

- More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes.

- About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year.

- More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness.

- If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people.

- Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection.

- And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will

declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

We urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. And by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) engaging community partners to tackle these issues.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen

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President, Health Care Without Harm & Practice Greenhealth

www.noharm.org

Contact: Emma Sirois, National Director, Healthy Food in Health Care Program, esirois@hcwh.org

MUC2021-134 Screen Positive Rate for Social Drivers of Health

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting Program, Merit-based Incentive Payment System (MIPS)

Workgroup
Hospital

Measure Description
Percent of beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety.

Numerator
Number of beneficiaries 18 and older that screen positive for food insecurity, housing instability, transportation needs, utility assistance or interpersonal violence.

Numerator Exceptions
N/A

Denominator
Total number of beneficiaries 18 and older screened for food insecurity, housing instability, transportation needs, utility assistance or interpersonal violence.

Denominator Exclusions
N/A

Denominator Exceptions
N/A

State of development
Field Testing

State of Development Details
Using a standard, validated screening tool, Accountable Health Community (AHC) has screened nearly 1 million beneficiaries for Health-Related Social Needs (HRSN) in 21 states, with 33% of beneficiaries screened having at least one HRSN.

-Sources:

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

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https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening.

-Sources:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Addiction medicine; Addiction medicine; Allergy/immunology; Behavioral health; Cardiac electrophysiology; Cardiac surgery; Cardiovascular disease (cardiology); Critical care medicine (intensivists); Dermatology; Emergency medicine; Endocrinology; Family practice; Gastroenterology; General practice; General surgery; Geriatric medicine; Gynecological oncology; Hematology/oncology; Hospice and palliative care; Infectious disease; Internal medicine; Interventional pain management; Medical oncology; Nephrology ;Nursing Homes; Obstetrics/gynecology; Osteopathic manipulative medicine ;Otolaryngology ;Pain management; Palliative care ;Pediatric medicine; Physical medicine and rehabilitation ;Podiatry ;Preventive medicine ;Primary care; Psychiatry; Public and/or population health; Pulmonary disease; Pulmonology; Radiation oncology; Rheumatology

Measure Type
Other

Is the measure a composite or component of a composite?
No

If Other, Please Specify
Social and Economic Determinants

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Clinical Data (non-EHR); Standardized Patient Assessments; Patient Reported Data and Surveys

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician; Group; Facility; Other: Beneficiary, Population

In which setting was this measure tested?
Ambulatory/office-based care; Behavioral health clinic or inpatient psychiatric facility; Community

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hospital; Emergency department; Federally qualified health center (FQHC); Hospital outpatient department (HOD); Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Equity

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
The measure correlates to specific MIPS Quality Improvement Activities as follows:

- Use QDCR data for ongoing practice assessment and improvements (IA_PSPA_7)
- Use of toolsets or other resources to close healthcare disparities in communities (IA_PM_6)
- Practice Improvements that Engage Community Resources to Support Patient Health (IA_CC_14)
- Provide Clinical-Community Linkages (IA_PM_18)

-Source:

https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2021

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
In COVID-19's wake, food insecurity, housing instability, IPV, and other basic DOH have reached unprecedented levels – and revealed searing racial disparities. In 2021, 21% of Black individuals are projected to experience food insecurity, compared to 11% of white individuals. Likewise, 22% of Asian, 22% of Black, and 20% of Latino renters are not caught up on rent, compared to 9% of white renters.

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Secretary Becerra has pledged “to take a department-wide approach to the advancement of equity, consistent with President Biden’s charge to federal departments and agencies, and this would include examination of ways to address the social determinants of health.” In particular, he has noted the importance of collecting more robust DOH data to address the disparities exposed by COVID-19 and leveraging the data and experience from the CMMI Accountable Health Community (AHC) model, which has screened nearly one million beneficiaries.
CMS has recognized the importance of making DOH measures standard across programs, identifying the development and implementation of “measures that reflect social and economic determinants” as a key priority and measurement gap to be addressed through Meaningful Measures 2.0.

A growing set of constituencies have called on CMS to provide leadership in measuring and addressing DOH, citing various rationales for doing so. Healthcare experts have increasingly recognized that equity is unachievable without addressing DOH, calling for CMS to require program “participants to uniformly screen for and document drivers of health” and “build DOH measures into MIPS and all APMs.” The Health Care Payment Learning & Action Network (LAN) – a group of public and private health care leaders providing thought leadership, strategic direction, and ongoing support to accelerate adoption of APMs – has identified promoting equity and addressing DOH as key facets of APM resiliency.

Likewise, physicians and other providers have called on CMS to create standard patient-level DOH measures – beyond socioeconomic status (SES), hierarchical condition category (HCC) score, or duals status – recognizing that these risk factors transcend specific subpopulations; drive demand for healthcare services; escalate physician burnout; and penalize physicians caring for those patients via worse Merit-based Incentive Payment System (MIPS) scores.

-Sources:
https://www.feedingamerica.org/sites/default/files/2021-03/National%20Projections%20Brief_3.9.2021_0.pdf
https://www.cbpp.org/research/poverty-and-inequality/tracking-the-covid-19-recessions-effects-on-food-housing-and

https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization

https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

https://www.healthaffairs.org/do/10.1377/hblog20201216.672904/full/

https://hcp-lan.org/2021-roadshow-deck/

https://physiciansfoundation.org/wp-content/uploads/2020/11/PF-QPP-Open-Comment-Submission-v.f_-.pdf

https://pubmed.ncbi.nlm.nih.gov/27942709/

https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf

https://pubmed.ncbi.nlm.nih.gov/30610144/

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https://pubmed.ncbi.nlm.nih.gov/32897345/

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program being submitted as-is for a new or different program

Range of years this measure has been used by CMS Programs
Accountable Health Communities Pilot (2017-2022)

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program is your measure similar to and/or competing with?
N/A

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How will this measure be distinguished from other similar and/or competing measures?
N/A

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
See attached document "Peer Reviewed Evidence and Relevant Research_MUC2021-134_Physicians Foundation_5 27 21.pdf" with supporting evidence and research.

Evidence that the measure can be operationalized
•CMS has the opportunity to leverage and apply CMMI's 5+ years of data and experience with AHC. Using a standard, validated screening tool, AHC has screened nearly 1 million beneficiaries for HRSN in 21 states, with 33% of beneficiaries screened having at least one HRSN. AHC used screening, referral, and navigation data files extracted by NewWave (Centers for Medicare & Medicaid Services [CMS] Enterprise Portal contractor) and generated by Mathematica Policy Research (the AHC implementation contractor) using data submitted by bridge organizations.

-Sources:

https://innovation.cms.gov/innovation-models/ahcm

https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf

https://innovation.cms.gov/media/document/ahc-fact-sheet-2020-prelim-findings

A number of CMMI models and participating entities have incorporated DOH screening and navigation data into their quality frameworks and care management plans for beneficiaries. CMMI's Comprehensive Primary Care Plus (CPC+) model reported in 2020 that 86% of ~1,500 Track 1 practices and 99% of ~1,500 Track 2 practices (together serving ~2.4M beneficiaries) are implementing DOH screening. CMMI required that by Program Year 3, Track 2 practices would use an electronic screening tool to assess patients' health-related social needs and store an inventory of resources to meet patients' needs; notably, by Program Year 2, Track 1 practices were as likely as Track 2 practices to report implementing these DOH functions, even absent a requirement that they do so.

-Source:

https://innovation.cms.gov/data-and-reports/2020/cpc-evaluation-annual-report-2

Likewise, annual evaluations of other current CMMI models, including the State Innovation Model and Next Generation ACOs, report that participants are investing in staffing and infrastructure to conduct DOH screening and navigation. The 2021 Comprehensive End-Stage Renal Disease Care Model

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evaluation, for example, reported that "[m]any beneficiaries are protein malnourished and don't eat enough fresh produce. Some beneficiaries go to the hospital to get meals." ESRD Seamless Care Organizations have begun to monitor food insecurity and provide food gift cards to both low-income beneficiaries and those above the poverty level, to address beneficiaries' non-adherence to nutritional guidelines and reduce the risk of increased utilization and costs.

-Sources:

https://downloads.cms.gov/files/cmmi/sim-rd2-test-ar3.pdf

https://innovation.cms.gov/data-and-reports/2020/nextgenaco-thirdevalrpt-fullreport

https://innovation.cms.gov/data-and-reports/2021/cec-annrpt-py4

How is the measure expected to be reported to the program?
eCQM; Claims

Feasibility of Data Elements
Some data elements are in defined fields in electronic sources; Patient/family-reported information: electronic; Patient/family-reported information: paper

Evidence of Performance Gap
CMS has already identified social and economic determinants as both a measurement priority and gap in Meaningful Measures 2.0. Other public and private organizations such as ASPE, NQF and NCQA have identified this as a critical gap.
-Sources:
https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization
https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress
https://www.qualityforum.org/News_And_Resources/Press_Releases/2019/National_Quality_Forum_Leads_National_Call_to_Address_Social_Determinants_of_Health__through_Quality_and_Payment_Innovation.aspx
https://blog.ncqa.org/ncqa-releases-its-social-determinants-of-health-resource-guide/

Unintended Consequences
A potential unintended consequence of the measure is that health systems and hospitals will not be equipped to act on it due, in part, to the lack of community resources. This challenge was noted as a primary barrier to connecting beneficiaries to resources in the AHC Year 1 evaluation. There is a well-documented and well-tested catalog of additional tools, infrastructure, and investments that can be implemented to support practices in acting on this measure.

-Sources:
https://fhop.ucsf.edu/sites/fhop.ucsf.edu/files/custom_download/Unintended%20consequences%20of%20screening%20for%20social%20determinants.pdf
https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt
https://nhchc.org/wp-content/uploads/2020/04/NHCHC_Community-Information-Exchange2.pdf
https://governor.nc.gov/news/north-carolina-creates-nation%E2%80%99s-first-statewide-infrastructure-connecting-healthcare-and-human
https://blueshieldcafoundation.org/sites/default/files/publications/downloadable/Investing%20in%20Health%20-%20A%20Federal%20Action%20Plan%20-January%202021_Final.pdf

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Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
No

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
N/A

Type of Evidence to Support the Measure
U.S. Preventive Services Task Force (USPSTF) Guidelines; Systematic Review; Empirical data

Is the measure risk adjusted, stratified, or both?
Stratified

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Extensive research exists demonstrating increased healthcare expenditures to patients including Medicare beneficiaries associated with DOH. The example below provides the annualized increase in annual healthcare expenditures (PMPY) associated with food insecurity across different disease categories across all payor types in the peer-reviewed literature:

- Diabetes Mellitus: $4,413.61
- Hypertension: $2,175.20
- Heart Disease: $5,144.05
- Overall: $1,863

-Source:
https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf
The AHC Year 1 evaluation found that Medicare FFS beneficiaries in the Assistance Track intervention group had 9% fewer ED visits than those in the control group in the first year after screening. (No Medicaid utilization/cost data reported yet.)
-Source:
https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt

Cost Avoided Annually by Medicare/Provider
Unable to determine – though the cost avoided annually is likely to be significant given the research demonstrating increased utilization, readmissions, cost and increased financial liability for providers caring for patients with increased social risk.

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Source of Estimate
Sources:
https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf
Also see attached review of the research literature for additional cost studies related to DOH.

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Surveys

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
3162

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2441

Burden for Patient: Does the measure require survey data from the patient?
Yes

If yes, what is the estimated time to complete the survey?
0

If yes, what is the frequency of requests for survey data per year?
1

If yes, are the survey data to be collected during or outside of a visit?
Prior to visit; During visit; After visit

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys; Focus groups; Standard TEP

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Total Number of Clinicians/Providers Consulted
10078

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
8800

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
3224

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
3

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
These results are the first to suggest that both the AHC and YCLS have high reliability and concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to engage in social risk-informed care.
-Source:
https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/#ref38

Type of Reliability Testing
Measure Score Reliability; Data Element Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
1008

Reliability Testing Statistical Result
Within social domains, percentages reporting a social risk tended to be higher by the AHC than the YCLS. Using unadjusted kappas, the AHC and YCLS items had substantial agreement for measures of

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food insecurity only. When examining the adjusted kappas that account for bias and prevalence, agreement between the AHC and YCLS items was substantial or higher (kappas > 0.60) for all social risks except housing quality (kappa = 0.52). The YCLS and CHW had substantial agreement (kappa 0.75) on housing.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Internal Consistency; Predictive Validity; Other: Empirical validity (through AHC and CPC+ practice implementation across 3+ million beneficiaries over last ~5-year time frame) and Psychometric and Pragmatic Property Analysis (see https://pubmed.ncbi.nlm.n)

Validity Testing Sample Size
Study 1: 1,008 ; Study 2: 30,098 ; Study 3: 60,000

Validity Testing Statistical Result
Study 1: A reported social risk on the AHC and YCLS measures was strongly associated with having fair or poor self-rated health
-Source:
https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg
Study 2: HFSS questions 1 and 2 were most frequently endorsed among food-insecure families (92.5% and 81.9%, respectively). An affirmative response to either question 1 or 2 had a sensitivity of 97% and specificity of 83% and was associated with increased risk of reported poor/fair child health (adjusted odds ratio [aOR]: 1.56; P < .001), hospitalizations in their lifetime (aOR: 1.17; P < .001), and developmental risk (aOR: 1.60; P < .001).
-Source:
https://pubmed.ncbi.nlm.nih.gov/20595453/
Study 3: Sensitivity of each two-item combination was high for the US population and high-risk demographic groups compared with the eighteen-item CFSM (Table 2). Sensitivity ranged from 96·4 % for items 2 and 3 for households with children and incomes <200 % of the federal poverty line, to 99·8 % for items 1 and 3 for Spanish-speaking households. (results for all combinations are available from the corresponding author upon request). Specificity was lower, ranging from 73·7 % for items 1 and 2 for households with children and incomes <100 % of the federal poverty line, to 94·5 % for items 2 and 3 for households with a respondent aged >60 years. Accuracy was high for all two-item combinations.
-Source:
https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Validity Testing Interpretation of Results
Study 1: These results are the first to suggest that both the AHC and YCLS have concurrent and predictive validity, supporting their use in healthcare settings, including by primary care physicians to

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engage in social risk-informed care.

-Source:

https://www.jfmpc.com/viewimage.asp?img=JFamMedPrimaryCare_2020_9_9_5026_296311_t6.jpg

Study 2: A 2-item FI screen was sensitive, specific, and valid among low-income families with young children. The FI screen rapidly identifies households at risk for FI, enabling providers to target services that ameliorate the health and developmental consequences associated with FI.

-Source:

https://pubmed.ncbi.nlm.nih.gov/20595453/

Study 3: The test characteristics of multiple two-item combinations of questions assessing food insecurity had adequate sensitivity (>97 %) and specificity (>70 %) for widespread adoption as clinical screening measures.

-Source:

https://www.cambridge.org/core/journals/public-health-nutrition/article/brief-assessment-of-food-insecurity-accurately-identifies-highrisk-us-adults/81A4F5E162241E289A5181A10C056125

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
33%

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
Other

Measure Steward Contact Information
Robert Seligson
4033 Lila Blue Lane
Raleigh, NC 27612
bob@physiciansfoundation.org
919-306-0056

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Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis –MUC2021-134 Screen Positive Rate for Social Drivers of Health

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure assesses the percentage of patients who screened positive for health-related social needs, which is consistent the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants. There are no similar measures in the Hospital IQR Program.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: No

Justification and Notes: Studies have shown that providers who care for patients with higher social risk scores tend to have lower performance scores in quality-of-care programs (Khullar et al., 2020). However, that causal relationship is not clear. The measure ultimately seeks to bridge patients screened positive for health-related social needs with community navigation services and an individualized action plan from the beneficiary to resolve HRSNs identified by the screening. However, the measure does not guarantee that this connection will be made.

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: The measure is conceptually related to a critical quality challenge. The developer notes that identifying and addressing social determinants of health has become a top nationwide priority for leaders in healthcare. According to Fraze et al (2019), just 16 percent of physician practices screened patients for all five social needs identified in this measure, and 33 percent of practices did not screen patients for any needs. In the 2017-2020 years of evaluation of a CMS program based on the measure's screening tool, 34% of beneficiaries screened were positive for at least one need. Although the measure assesses the proportion of a hospital's patient population that has an unmet social need, the measure does not specifically address screening rates or follow-up after a positive screen.

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Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: There are no similar measures in the Hospital IQR Program related to social determinants of health or screening. However, it is unclear how patients can use the results of this measure in the Hospital IQR program as currently specified.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: To report the measure, providers must collect the number of patients who were screened for all five elements and the number who screened positive for at least one item; the only demographic information needed is patient age. The screening tool data can be electronically collected and recorded; therefore all data points should be available to providers for reporting. The screening tool has been in use in 21 states across the US, with nearly one million patients screened.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure has been specified and trialed in several settings, including hospital inpatient acute care facilities. The MAP should note that although the reliability and validity has been examined for the screening tool, no such testing has been evaluated for the measure as 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 been identified?

Yes/No: Yes

Justification and Notes: Because the measure itself has not been tested, no unintended consequences have yet been identified by stakeholders. However, the developer notes one unintended consequence is that health systems and hospitals may not be equipped to act on it. This could lead to frustration for both patients and providers as well as ethical challenges (Garg et al., 2016). Additionally, the measure may create incentives for hospitals to avoid screening patients who are most likely to test positive for a social need.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

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Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- There was some discussion on what the relevance of this measure is if there is no link to payment, as the screening rate measure would accomplish the data collection issue

Data collection issues:

- None

Calculation issues:

- There was similar concerns with the screening rate measure (MUC-136).
- There was some concern on whether the positive rate is standardized. The developer responded that since the screening is standardized, then the positive indicator would also be standardized

Unintended consequences:

- There was some discussion on what the impact of a measure on payment to providers.
- Concerns were raised regarding the capture of a positive screen without the appropriate resources available to support the patient needs.

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.5
1 – 0 votes
2 – 2 votes
3 – 3 votes
4 – 7 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This is supplemental to the screening measure (MUC-136), as it will report the populations that have been screened
- There was discussion that what good performance would be. The developer stated that this should be included in a pay for reporting measure and that there are no thresholds for what "good" looks like.
- The variability of the measure makes this very challenging and will make this difficult to compare across practices and over time
- It is not fully baked for its intent, and even the intent is very unclear

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

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- The unintended consequences is that facilities with resources will potentially capture more "needs" in a disproportionate fashion
- Similar concern to MUC-136 in that there is an expectation that is set up when these questions are asked, and if there are processes in place there would be frustration felt by providers and patients. Identification without resources is not helpful. There needs to be a standardized approach.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.7
1 – 0 votes
2 – 3 votes
3 – 5 votes
4 – 9 votes
5 – 4 votes

Recommendation

Preliminary Analysis Recommendation:

Do Not Support for Rulemaking with potential mitigation. Mitigation identified includes updates to the measure to capture linked, actionable interventions by the accountable entity and NQF endorsement of the measure.

Summary: What is the potential value to the program measure set?
This measure assesses the percentage of patients who screened positive for health-related social needs. It would be the first in the Hospital IQR Program to specifically address screening for social determinants of health, which is consistent with a Meaningful Measures 2.0 priority.

Summary: What is the potential impact of this measure on quality of care for patients?
The measure ultimately seeks to bridge patients screened positive for health-related social needs with community navigation services and an individualized action plan from the beneficiary to resolve HRSNs identified by the screening. However, the screening measure does not contain any data or requirements to ensure this follow-up. MAP expressed concern that the positivity rate may be challenging for consumers to interpret when publicly reported. The measure has not been evaluated for reliability or validity.

Section 3: Public Comments

NewWave
Both MUC2021-136 (Driver of Health Screening Rate) and MUC2021-134 (Driver of Health Screen Positive Rate) are important baby-steps to begin measuring drivers. They are simple process measures that may be valuable in starting the measures we really need to be working toward. Knowing the rate of Screening and of those screened which had positive indicators of food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety will do little to improve the rate at

which we implement programs that have a meaningful\measurable impact on effecting this QOL deteriorating drivers that rob value from any health care delivery received by effected individuals.

It is critical that these "conversation starter measures" are not considered an end in themselves but are in fact simple measures that we can do today with little controversy or change in the as is state of the care delivery system. Until we begin to measure the closed loop referral process and gather population level impacts and gaps the value of measures of drivers will be little more than the minimum we must be doing to get started on the more important work to be done to address the blockers to better inter-sector and interoperable whole-person care that is called for by everyone.

findhelp
MUC2021-134 (Driver of Health Screen Positive Rate) MUC2021-136 (Driver of Health Screening Rate)
Re: Comments for NQF public comment period on CMS MUCs

In response to the National Quality Forum (NQF) public comment period on Centers for Medicare & Medicaid Services' (CMS) measures under consideration (MUCs), please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation.

About findhelp

Founded in 2010, findhelp, a Public Benefit Corporation runs the largest social care network in the United States and has served more than eight million Americans. Our mission is to connect all people in need with the programs that serve them with dignity and ease. As part of fulfilling this mission, we will always maintain findhelp.org, a free and anonymous search tool for identifying free and reduced cost programs in every U.S. zip code. Our network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as tens of thousands of Community Based Organizations (CBOs). Findhelp's interoperable social care technology works with electronic health records (EHRs) and other platforms to help clinicians and other partners address the social needs of individuals in a seamless fashion.

Comments

Findhelp appreciates the opportunity to share feedback with NQF related to proposed quality measures specific to Social Drivers of Health (SDoH).

1. This measure recognizes social needs screening as an important clinical tool.

Recognizing the value of Social Drivers of Health (SDoH)

Screening for SDoH provides clinicians with actionable data on health-related social needs that may be impacting the whole person of their patients. Capturing SDoH risks and screening information can better inform provider organizations about the needs of their patients and communities. This information can help healthcare organizations connect patients to needed resources, prioritize partnerships with CBOs and vendors, and inform capacity planning.

For example, findhelp customer Boston Medical Center (BMC) developed the THRIVE SDoH Screening and Referral program to identify and address detrimental social factors preventing patients from

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thriving, such as unstable housing, food insecurity, financial instability, and other issues. Through the THRIVE screener, patients identify their social needs, and BMC staff refer them to both resources at BMC and in the community using the THRIVE Directory (powered by findhelp).

Governments at all levels make significant resources available to consumers related to their social needs. Such resources could include, but are not limited to, those used to address food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Yet, a clinician's ability to support a patient is only as strong as his or her awareness of the patient's needs. Screening for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety gives providers the opportunity to impact a patient's health in ways far beyond clinical interventions.

Unfortunately, connecting those resources to consumers who need them – including the nation's Medicare and Medicaid beneficiaries – can be challenging. We encourage CMS to make identifying social care needs and connecting these consumers to available resources a core part of their healthcare quality and health equity strategies moving ahead.

Incentivizing measurement of SDoH

In particular, we encourage CMS to adopt MUC2021-134 and MUC2021-136 into federal payment programs. These will be the first standard SDoH measures included in federal payment programs and will provide a starting point to incentivize healthcare providers to measure and report on patients' SDoH needs.

2. The benefits of the measure outweigh the burden of data collection and reporting.

Data collection is both valuable and feasible

We believe that not screening for SDoH represents a larger burden to providers than conducting the screenings. Not building SDoH measures into the health system increases the burden on physicians as SDoH are still part of their patients' clinical reality. As healthcare providers increasingly recognize the impact of SDoH on their patients and practices, especially in light of COVID, they have called for CMS to measure what matters.

While this screening work is happening around the country already, there is a strong need for a national standard for this process. In the absence of CMS SDoH measures, physician organizations (e.g., findhelp customers American Academy of Family Physicians and American Academy of Pediatrics) have developed ad hoc SDoH screening guidelines. More than 100 findhelp customers currently using our platform to screen patients for SDoH needs, and many more screen directly in their EHRs and care platforms.

CMS has already implemented these measures in a limited fashion, providing NQF and other stakeholders an opportunity to review the tangible impact to clinicians of undertaking the screening. The measure developer (the Physicians Foundation) submitted these SDoH measures because they are currently in use in the CMS Innovation Center's Accountable Health Communities model, where they have been effectively tested and implemented over 5 years with nearly a million CMS beneficiaries in

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600 clinical sites and multiple practice settings across the country.

Interoperability of social care networks

After screening patients for SDoH needs, many healthcare provider organizations will want to facilitate the connection of their patients with needed services. To facilitate this vital next step, the technology exists to integrate social care referrals into EHRs or other platforms. Through platforms such as findhelp, healthcare systems, providers and CBOs are able to receive and exchange social care data from various sources within their own environment and systems of record.

CyncHealth

The proposed measures are a step in the right direction. As a health information exchange (HIE), we recognize that these measures add value to both the community and providers. They allow for the community to become more aware of the social needs that are prevalent in the community, and for providers to have better data for reporting. This increased awareness and data allows for an improvement in cross-sector partnerships to occur that empowers providers and communities to collaborate and advocate for polices that support equity in their communities.

As an HIE, we would use the measures to do regulatory reporting on behalf of the providers we serve. The benefit of these measures will be determined by the effective implementation of the measure. The biggest challenge to implementation of these measures is a lack of standardization. There should be serious consideration given to adapt a universal screening tool, so that outcomes can be measurable and consistent across the board. A failure to adapt a standardize screening tool will result in inconsistent outcomes. Currently depressions screenings are standardized to the PHQ and that allows for measurable and consistent outcomes to be reported. The same level of standardization needs to be applied to these proposed measures. The consistency of measurable outcomes that standardization will provide will enable the development of a good tool and provide a real-world benefit that outweighs the burden of data collection or reporting.

National Produce Prescription Collaborative

December 9, 2021

To: Members of the NQF: Measure Applications Partnership From: Members of the National Produce Prescription Collaborative (NPPC)

*SUBMITTED TWICE *

RE: Support for Driver of Health Screening Rate (MUC2021-136)

*Re: Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the “Drivers of Health Screening Rate” and the “Drivers of Health Screening Positive” measures as part of the 2021 CMS MUC list, and recommend that you move them forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle.

Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of

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these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its "measures under consideration" list this year. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through our federal health programs.

As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people's diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long standing burden of diet-related chronic disease. Unfortunately, these diet-related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

If approved, this measure would apply to two key Medicare programs — the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — and improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, we see adoption of this measure as a pathway for Produce Prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs

The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country. A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions

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improve improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers. Having DOH measures available to screen for food insecurity will help these government-sponsored health plan practitioners deliver on the growing promise of food as medicine. For example: In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity. Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercised regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020. Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare, and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward for consideration.

About NPPC

The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce

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Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and who are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

Montefiore Health System

Yes; support for inclusion in the program

Blue Shield of California Foundation

The COVID-19 pandemic has exposed long-standing racial and economic injustices embedded in our health care system. This has led to a renewed commitment to improve health equity and address the drivers of health (DoH) that account for 80 percent of health outcomes and have a disproportionate impact on communities of color. These include stable, affordable housing; healthy food; reliable income; and interpersonal safety, among others.

Advancing health equity and addressing DoH will require changing how and what we measure in health care. Measurement matters because it equips providers with data to identify and address unmet needs and allows policymakers and payers to account for DoH in payment models.

We thus strongly encourage the Measure Applications Partnership to support for rulemaking both MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021-136 (Screening for Social Drivers of Health).

Despite the well-documented impact of DoH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DoH measures in any Centers for Medicare &Medicaid Services' (CMS) programs. Even without such measures, the impact of DoH interventions are much-referenced in the health care discourse and literature, but remain functionally invisible in federal health care policymaking.

For example, a growing number of CMS Innovation Center models – Accountable Health Communities (AHC); Comprehensive Primary Care Plus; Maryland Total Cost of Care; State Innovation Models Round 2; and more – have screened millions of Medicare and Medicaid beneficiaries for DoH in thousands of inpatient and outpatient clinical settings across the country, but largely without the benefit of standard DoH screening tools or measures from CMS. As a result, CMS cannot systematically compare or use the data.

Recognizing the absence of DoH and race and ethnicity data as an issue, incoming CMS leadership in August 2021 cited the need for "patient-level demographic data and standardized social needs data" as a key element in its commitment to embedding equity in all models and demonstrations. The recently released CMS Innovation Center strategy report took this a step further by saying all new models will require participants to collect and report beneficiaries' demographic data and social needs data, when

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appropriate. Providers have joined the call for standardized, patient-level data collection for DoH, citing the impact of these drivers on patients, health care costs, and physician burnout.

These proposed DoH measures have been used in more than 600 clinical practices through the AHC model and have been subject to rigorous and independent validation. The AHC model found that 74% of navigation-eligible Medicare and Medicaid beneficiaries who were screened using these DoH measures opted in for navigation, nearly twice the projected estimate of 40%. Likewise, a large study in 2020 by Kaiser Permanente found that 85% of patients were in favor of health systems asking patients about social needs, and 88% were in favor of health systems helping to address those needs.

The introduction of the first DoH measures into core federal payment programs would be significant in its own right – making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all.

If approved, these DoH measures can be improved over time through CMS's annual measure review process and can provide the groundwork for comparable measures for the Medicaid and CHIP Child and Adult Core Sets and guidance for states in their efforts to standardize DoH data. Further, these initial DoH measures could lay the foundation for subsequent measures focused on ensuring patients secure the resources they need to be healthy and accelerating/enabling investments in community capacity. In particular, these DoH measures will provide crucial data on the prevalence of unmet social needs among beneficiaries and other learning to enable more effective public and private sector investments in the technical/IT infrastructure, community-based navigation workforce, and capacity building and sustainable sources of funding necessary to enable the equitable integration of healthcare and community social services.

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Academy of Nutrition and Dietetics

The Academy of Nutrition and Dietetics' (Academy) Strategic Plan has a focus area dedicated to the topic of food insecurity- Nutrition Security and Food Safety. Within that focus area, there are impact goals: Advocate for equitable access to safe and nutritious food and water, and Advance sustainable nutrition and resilient food system. Therefore, the Academy is focused on impacting the health and wellbeing of individuals impacted from food insecurity, a component of the quality measure.

A concern with this proposed measure is it is not outcomes based. What happens with care once the individual is screened? What interventions are proposed to improve care? These outcomes are

important so that care is impacted, not just data collected.

Food insecurity and malnutrition are widespread and worsening issues in the United States. Both food insecurity and malnutrition are associated with negative health outcomes and higher spending on health care. Adults who are malnourished at the time of hospitalization or surgery are more likely to have worse hospitalization, surgery, and recovery outcomes. Registered dietitian nutritionists (RDNs) have a responsibility to identify and address nutrition and food insecurity.

The purpose of a food insecurity screen, which is a component of the Accountable Health Communities Health-Related Social Needs Screening Tool, is to quickly identify households at risk for food insecurity, allowing providers to target services and interventions that address the health and developmental consequences of food insecurity.

RDNs working in health care settings, e.g., hospitals, long-term care, residential care, or free-standing dialysis facilities actively address discharge planning needs directly or in collaboration with a social worker or care coordinator to achieve improved outcomes for patients/clients and the organization, e.g., avoid hospital readmission. In addition to RDNs working in health care settings, RDNs in community nutrition or population health conduct population health management to achieve improved clinical health outcomes of the community/population.

The Academy has created a Practice Tips: Addressing Food and Nutrition Security (https://www.eatrightpro.org/practice/quality-management/competence-case-studies-practice-tips) to help RDNs assist patients/clients with these issues and to improve the health of the community at large.

Institute for Healthcare Improvement (IHI)
Public Statement on 2021 CMS Measures Under Consideration:

Drivers of Health December 8, 2021

Today we know that social factors influence health outcomes. We also know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health (DOH). In COVID-19's wake, food insecurity, housing instability, interpersonal violence, and other DOH have reached unprecedented levels and revealed massive racial inequities. In 2021, 21% of Black individuals are projected to experience food insecurity, compared to 11% of white individuals. Likewise, 20% of Asian, 28% of Black, and 18% of Latino renters are not caught up on rent, compared to 12% of white renters (references below.)
The challenge now is to figure out how to work on these drivers of health in a fundamentally different way. In this context, it is untenable for the health care system to continue to address DOH primarily through special pilots or initiatives, as the National Academies of Sciences, Engineering, and Medicine (NASEM) demonstrated in their report, "Integrating Social Care into the Delivery of Health Care: Moving Upstream to Improve the Nation's Health."

Consistent with recommendations in the NASEM report, we are pleased that CMS has included two beneficiary-level DOH measures (MUC2021-134: Screen Positive Rate for Social Drivers of Health and MUC2021-136: Screening for Social Drivers of Health) on the Measures Under Consideration list in the equity domain. These measures should be recommended by the Measure Applications Partnership (MAP) in this review cycle, as a reflection of HHS' and CMS' commitment to equity and addressing the

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health-related social needs of the millions of beneficiaries they serve.

These measures, stratified by race/ethnicity, are (1) crucial to identify racial disparities in DOH, including those driving health inequities; (2) will lay the foundation for health care institutions to help guide beneficiaries to the resources they need to be healthy; and (3) will lead to more accurate risk adjust payment models. Drivers of health screening are also crucial in creating the imperative for public and private investments in the workforce and technology needed to reliably connect beneficiaries to the resources they need. And, most importantly, these measures can help ensure those resources exist in the first place, through cross-sector and community-based partnerships.

In 1999, the Institute of Medicine published To Err is Human in part to "…reveal the often startling statistics of medical error." That report did not promise easy solutions, but it asserted that it was time to "…break the silence that has surrounded medical errors and their consequence." Similarly, it is time to make visible the reach and impact of DOH by enacting the first-ever DOH measures in federal payment programs.
Citations:
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Legacy Community Health
For the first time, CMS is considering two quality measures related to social risk screening as part of this year's 44 new Measures Under Consideration (MUCs) list. The two measures are: Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136) Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134).

We have been screening for these measures for years and have found them to be a key driver in health outcomes. It would be helpful to have a standardized approach so that we can further our efforts of proving that social determinants of health are just as important to overall health as traditional healthcare.

Missouri Hospital Association

The Missouri Hospital Association feels that the resources required to generate these data would be better used in the systematic capture of ICD-10 Z-codes related to SDOH in both electronic health records and uniform billing administrative claims data systems. CMS also should work with ICD-10 Cooperating Parties to include additional Z-codes currently in unrepresented domains of social vulnerability, such as access to reliable transportation.

Duke Margolis Center for Health Policy

The Duke-Margolis Center for Health Policy encourages the inclusion of measures addressing social drivers of health (SDoH) in CMS quality reporting programs. The impact of these drivers on health is well

documented, and a growing number of efforts are under way to examine how health care providers and organizations can better identify and address individuals' SDoH-related needs. Among these efforts are those examining how to leverage value-based payment (VBP) models to better address SDoH.1 Our work has found VBP models have the potential to support the infrastructure and cross-sector relationships needed to identify and comprehensively address SDoH-related needs.2 However, the current dearth of SDoH-related quality measures makes it difficult to embed accountability for addressing SDoH into VBP models. Development and implementation of SDoH-related quality measures are needed if VBP efforts to meaningfully address SDoH are to be successful.

The addition of the MUC2021-136 and MUC2021-134 measures to the Hospital Inpatient Quality Reporting Program and Merit-based Incentive Payment System would reflect the emphasis needed on advancing SDoH-related quality measures, especially if they can be clearly linked to a strategy for supporting improvement in the SDOH risk factors reflected in such measures. Such a strategy should include more systematic collection and reporting of SDoH-related data, development of the infrastructure needed to support partnerships across sectors (e.g., health care, education, justice), and implementation of payment models that can support and sustain the delivery of SDoH-related services. The inclusion of SDOH-related quality measures in CMS quality reporting programs is one way to support progress in implementing such a strategy.

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Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the development and implementation of measures that seek to address inequities in care and those factors that may directly or indirectly impact an individual's ability to achieve positive health outcomes. Regrettably, the FAH is unable to support the inclusion of this measure in the Hospital Inpatient Quality Reporting (IQR) Program for several reasons.

While the FAH supports the overall intent of this measure and MUC2021-136, Screening for Social Drivers of Health, we were unable to determine why the specific social drivers of health were selected, the degree to which they are aligned with the work of the Health Level 7 Gravity Project or the United States Core Data for Interoperability (USCDI), and whether the intended patient population is Medicare beneficiaries or those aged 18 years and older since the wording is not clear. In addition, the developer did not provide any evidence demonstrating that this process is linked to improvements in health outcomes nor has testing of the measure been completed.

Furthermore, the FAH requests that the Hospital Workgroup consider the degree to which this measure could be considered actionable and the resulting performance scores should be attributed to a hospital. This measure assesses the rate of positive screens but does not appear to address the degree to which a

facility has been equipped with the necessary resources and tools to address the individual's needs. In the absence of this information, the FAH does not believe that a rate of positive screens will reflect the quality of care provided by a hospital.

The FAH believes that these questions and concerns must be addressed and endorsement by the National Quality Forum should be achieved prior to implementation of this measure in the Hospital IQR Program. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support."

American Medical Association

While the American Medical Association (AMA) supports the intent of this measure to begin to address the social drivers that can also impact an individual's health outcomes, we do not believe that the implementation of this process measure, in the absence of any resources or tools that would be widely and readily available to hospitals, should be pursued at this time. Measures must be actionable and facilitate improvements in patient care and a measure that only reports the rate of positive screens does not represent the quality of care provided by a hospital. While all hospitals can identify and facilitate addressing social needs, they cannot and should not be held responsible for resolving them. Other strategies such as stratification of populations by race, ethnicity, and social drivers of health should be employed. In addition, the developer did not provide any evidence to demonstrate that the collection of these data alone will drive improvements in health outcomes nor is it is clear why the developer selected the specific social drivers of health for this measure and MUC2021-136, Screening for Social Drivers of Health. The measure must be supported by evidence and should align with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). We were also unable to determine which patients the measure intended to capture since the word "beneficiaries" is typically used when a measure applies to those individual with Medicare Fee-for-Service, yet the denominator language also indicates that it would be any person 18 years and older. In addition, the measure itself is not yet tested. We believe that many of these discrepancies would be resolved if the measure was fully specified and demonstrated to be evidence-based, reliable, and valid. Because we do not believe that this measure will result in effective change, we request that the highest level of MAP recommendation be "Do Not Support."

The Coalition to Transform Advanced Care

We support this measure and very much appreciate its addition to the MUC list. We believe this will begin to gather this important information in a more systematic way and help to help build better links to community services that address these needs. '

Because this is a new area for measurement, we are not yet sure what application it will have but believe it will certainly inform QI efforts and could also be used for payment in value-based arrangements.

We see little implementation issues in gathering the information, which is what the measure requires, but hope that it will be the beginning of a more comprehensive way not only to screen for social drivers of health but to refer and then deliver any needed services. However, this is an important first step

Denver Regional Council of Governments

As the Project Director for one implementation of the CMMI Accountable Health Communities

Alignment Track Model, I support this measure with limitations. Simply put, only screening for social needs will not work for the hospital, clinical staff, or the patient. screening for social needs and not addressing the need is the same as diagnosing someone with diabetes and then not providing a prescription for insulin or instructions on how to use it. For this measure to be successful for the patient, the hospital must be required to connect the patient with a service that addresses the identified need. Additionally, any hospital that implements a program to achieve success on this measure should be required to partner with local community-based organizations to provide services to address the identified needs. The burden to implement this measure far exceeds the cost of implementation, data collection, and reporting. The benefit to the patients with needs is obvious and the benefit to the hospital and clinical staff include increased trust and engagement from patients as well as better outcomes.

Kaiser Permanente

KP supports development and adoption of reliable, evidence-based, well-tested measures of social drivers of health. KP currently measures social drivers with a standard instrument for quality and performance improvement, and we have set aggressive targets to rapidly expand standard screening across the enterprise. Our unique experience with implementation of these measures at significant scale with our 12.5 million members enables us to contribute to the evidence base for these measures, including impact on health, care, cost, and equity, and we will continue to do so through our robust social health research and evaluation efforts over the next few years. We recognize these upstream measures are new in the measure development and review process and may present special challenges. We offer our support and collaboration, and request to stay informed and connected throughout the process.

Children's HealthWatch, Boston Medical Center

Measure Applications Partnership (MAP)
Currently selected 2021 MAP Measures Under Consideration (MUC)
Comments submitted

On behalf of Children's HealthWatch, we applaud the National Quality Forum (NQF) Measures Application Partnership's consideration of MUC 2021-136 (Driver of Health Screening Rate) and MUC 2021-134 (Driver of Health Screen Positive Rate). Children's HealthWatch seeks to improve the health and development of young children and their families by informing equitable policies that address and alleviate economic hardships and by dismantling systems of institutionalized discrimination and inequity at the root of these hardships. Our work begins with research through interviewing caregivers of young children on the frontlines of pediatric care, in urban emergency departments and primary care clinics in five cities: Boston, Minneapolis, Little Rock, Baltimore, and Philadelphia. Since 1998, we have interviewed over 75,000 caregivers of children under four years of age and analyzed the data to determine the impact of social risk factors (individual-level adverse social determinants of health) and public policies designed to address those social risk factors on the health and development of young children and the well-being of their families. Specifically, our research focuses on the following: nutrition, housing, health care, child care, utilities, income and wealth, employment, Adverse Childhood Experiences and Experiences of Discrimination. Our research – in addition to that of others – shows that lack of access to basic needs is associated with poor child health and development, poor parental physical and mental health, higher child hospitalization rates, and learning and behavioral/emotional impairments. Health consequences are often compounded, as they are frequently experienced

simultaneously, often as a result of limited income and resources.

How would adding this measure add value? How would the measure improve patient outcomes?

Based on decades of our research, and the research of others, we stress the importance and value of measuring of social risk factors to identify and address unmet social needs (social needs differ from social risks insofar as they convey the patient's preferences and priorities regarding the social risk) and enable policymakers and agencies such as CMS and other payers to incorporate them in value-based payment models. The measures under consideration (MUC 2021-136, MUC 2021-134) also offer a valuable opportunity to provide a foundation for comparable measures for the Medicaid Adult and Child Core Measure Set and guidance for states in their efforts to standardize these data.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of measuring social risk factors far outweigh the burden of data collection and reporting. Numerous studies have shown relatively high acceptability of social needs screening and referral among both patients and providers (https://bit.ly/3rSik2v, https://bit.ly/3rOPlN5). Initial evaluation of the Accountable Health Communities (AHC) Model found that among navigation-eligible beneficiaries who reported unmet social needs, 41% had one unmet social need and nearly 60% reported having multiple unmet social needs. While research and implementation of social needs screening and intervention has grown substantially over the past decade, providers and health systems struggle with heterogeneous screening tools and interventions. This contributes to absence of consideration of unmet social needs in federal health care policymaking. The prospect of these two measures being utilized in Medicare public reporting and performance-based payment programs would be beneficial because they would both elevate the importance of these issues for health at the federal level and shed much needed light on social risk factors in a standardized way that allows for accurate comparison of data across settings and communities. Furthermore, if these measures are stratified by race and ethnicity and by age, policymakers and agencies will be prepared to effectively target resources and actions that advance health equity and address long-standing disparities in health outcomes.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

These measures (MUC 2021-136, MUC 2021-134) offer opportunities to be used for QI, maintenance of certification, payment, and public reporting.

We consider MUC 2021-134 to be an indicator of the identified risk of the population. Thus, the measure and specific screening tools included in the AHC questionnaire it relies on are not capable of disease surveillance or diagnosis of certain social risk factors precisely because the AHC questionnaire was designed as a screening tool and identifying social risk factors in clinical settings for diagnosis and intervention may require further assessment. . In fact, our research has identified significant discordance among the AHC questionnaire housing questions and Children's HealthWatch housing questions. The two tools captured different housing-related risks and contributed to different health consequences, which were relevant to different subpopulations. These findings demonstrate that the choice of question is important to identifying the specific risk. We raise this point to underscore that any screening tool will inherently have limitations and thus further discussion with health providers and thoughtful linkages to interventions are critically important next steps. Thus, the AHC questionnaire

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does not measure all possible forms of social risk but instead is designed to capture specific domains currently identified as prevalent risk factors in health care and public health literature. Given the fact that there never will be nor could there be a single social risk screening tool that identifies every health-related social need for every person, the evidence-based approach taken to develop the AHC tool along with its wide adoption over the past few years, indicates that it is the best option available for the purposes of accomplishing the goals of these measures.

We suggest creating a paired measure of improvement over time in the specific social risk factors dimensions as a better measure than simply a one-time measure of proportion, again stratified by race and ethnicity and age. This improvement measure is similar to what the NQF Measure Incubator project has developed for the forthcoming food insecurity measures (https://bit.ly/3pGLZt0). Further, also aligned with the NQF Measure Incubator project's forthcoming food insecurity measures, we suggest a paired measure on appropriate interventions that have occurred as a result of identification of unmet social needs on screening. Interventions need flexibility to adapt to local context, resources, and community needs, however, certain core principles and best practices can still be standardized. Without an intervention-focused measure, we miss opportunities to understand the landscape of programs and interventions that serve the needs of families, and coordinate strategies that target or improve interventions.

Any model of care that seeks to measure outcomes should focus measurement and evaluation on providers' and institutions' ability to effectively 1) measure and 2) address health related social risks or concern (e.g., food insecurity, housing instability, transportation). A recent report from the National Committee for Quality Assurance (NCQA) describe health care organizations' use of both process (i.e., the number of patients screened or referred) and outcome (i.e., improvement from a baseline, meeting quality targets, impact on health care utilization) measures to evaluate the impact of their overall strategy and specific interventions. This report also made note that the field currently focuses more on process measures for specific social needs rather than health outcomes and health care utilization outcomes. A broad set of outcome measures beyond process measures is an area for further exploration.

Are there implementation challenges?

Challenges do exist, including limited provider time to screen and intervene, lack of a multi-domain screening tool that encompasses any and all social risk factors individuals may experience, and ability of institutions to suitably identify needs and provide targeted resources. The CMS Innovation Center and its 5-year AHC Model, while still under way, is an encouraging approach that demonstrates the need and political will to address this critical gap. Beyond expansion of this model, the Improving Social Determinants of Health Act of 2021 is a promising legislative opportunity to address limited health care resources and challenges to implementation of effective value-based care. Supported by hundreds of professional health organizations and networks, health insurers, and community-based organizations, the Improving SDOH Act would enable health providers and systems to better coordinate, support, and align SDOH best practices and capacity building activities. In coordination with the Centers for Disease Control and Prevention, federal agencies such as CMS, and local public health departments, the Act would support these activities by ensuring that there are resources and policies in place to intervene effectively on unmet needs and their health correlates. Specifically, through increased funding opportunities, technical training, and evaluation assistance, scaled data collection and analysis, and identification and coordination of best practices, this act would increase the public health sector's

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capacity to engage with the health care sector and fully address SDOH priorities beyond temporary referrals and interventions. Efforts like these are important to ensure that health systems are not only supporting their patients in achieving holistic health, but that providers also have the systems and resources to do so in ways that are sustainable, evidence-based, and avoid harms to patients.

Do you recommend this measure?

Yes

UniteUs/NowPow, a wholly owned subsidiary of UU

Overall, Unite Us supports including measure 134 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. Including these measures will encourage clinicians/clinical staff to screen and track social drivers of health. We recommend that additional measures should be considered that evaluate if beneficiaries who screened positive receive services to address their social drivers of health in a timely manner. Assessing without addressing does not improve quality in a meaningful way. While we encourage the use of social driver measures, the Unite Us team have some concerns regarding the measure implementation, methodology and process. It is not clear whether all domains would need to be assessed (e.g. financial insecurity and housing and utilities, etc.) or any one of these domains could be assessed to meet the measure. It is unclear if 80% beneficiaries screened means 80% of people had at least one of these domains assessed (but some had financial insecurity assessed, some were assessed for transportation, or all were assessed for interpersonal violence and nothing else) or it means 80% of people had all of these domains assessed. The Unite Us team advocates for the latter approach, as it is a higher standard.

ZERO-The End of Prostate Cancer

On behalf of the all those managing prostate cancer and navigating prostate cancer care (now and in the future), ZERO - The End of Prostate Cancer submits these comments in support of identifying those who screen positive for specific social needs such as food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety in the Hospital IQR and the MIPS program. Research has shown that socioeconomic factors are a substantial driver in the racial/ethnic differences in prostate cancer across the cancer continuum from prevention to end-of-life care. Families managing a prostate cancer diagnosis and navigating prostate cancer care engage with several staff, providers, and administrators in the healthcare delivery system; and this process often proves to be very complex, and to be substantially influenced by the socioeconomic resources of the patient and on how well the care delivery system has integrated “social care” into medical care. Not surprisingly, generally racial/ethnic minority and low socioeconomic status patients have worse health outcomes as they navigate the healthcare/cancer care delivery system. To address this issue, there have been several recent efforts to facilitate the integration of screening and addressing patient social needs in health care delivery; yet, there is no agreed upon standard tool for screening patients. Thus, it is critical that CMS facilitates the integration of standard measures and creates a pathway for identifying those with the social needs proposed in this new measure; and create financial incentives and risk models/frameworks that recognize the social factors that contribute to worse health outcomes and increased costs for patients. The integration of the proposed measures facilitates the consistent screening of patient social needs and incentivizes providers and health care delivery systems to navigate patients to address those social

needs and to evaluate the impact of those efforts on patient health outcomes. These efforts are needed to identify and eliminate health disparities and work towards health equity.

Next Wave
This measure begins to close the loop for focusing in on addressing social needs. See also comments under MUC2021-136 for recommended details that could automatically be generated if collected electronically using ICD-10 Z-codes.

It could be captured by a composite ICD-10 Z-code if available, and/or the existence of detailed codes for WHICH needs are identified through the expanding number of health related social need Z-codes.

In addition, for future social drivers, CMS should consider aligning the time frames for applying for any new ICD-10 Z-codes and creation of the MUC list to avoid implementation delays. E.g. it is already past the deadline for applying for ICD-10 codes to begin collection October 1, 2022 when this MUC list is being considered.

Premier, Inc.
Premier does not support adoption of this measure. While we are supportive of an overall screening approach, we are concerned that this measure will evaluate providers on factors that are outside of their control. Additionally, data collected through this measure will not be actionable and will not show directionality. For example, it is unclear what a higher positive screening rate means for a provider when compared against others. We instead encourage CMS to focus on the development of the "Screening for Social Drivers of Health" measure, which will better assess steps that providers are taking to evaluate the social needs of patients.

Massachusetts Child and Adolescent Health Initiative
The Child and Adolescent Health Initiative is a multidisciplinary coalition in Massachusetts seeking to improve care and outcomes for children, with a primary focus on working with MassHealth (the state's Medicaid and CHIP agency) to assure that MassHealth insured children and their families get the care they need to optimize outcomes.

How would the measure add value?

Assessing health related social needs is an essential step in providing appropriate services to patients/beneficiaries. This assessment enables providers and their health care organizations to then ascertain whether the patient desires assistance in addressing identified needs and, if they do, link them to appropriate and effective services. The tally of needs in a population also points to the broader social needs in a community and can lead to interventions to address the root causes of those needs (what the World Health Organization considers the social determinants or social drivers of health). These are the two strategies being explored in the Accountable Health Communities (AHC) model by CMMI. Given the importance of social needs in influencing both short and long-term health, regular assessment by health care provider organizations in order to take action is a core element of high quality care. Equity is also one of the core dimensions of care as defined by the National Academy of Medicine; key aspects of promoting equity in care include assessing and acting upon social needs and assuring that other aspects of care are not contingent upon the level of social need.

The stand-alone value of the rate at which there is a positive screen for social needs, especially in the aggregate, is uncertain. An aggregate measure may be of value as an indicator of "risk" for either health

outcomes or health care costs, but would need much more research to be validated and compared to other social risk indicators already in use.

The level of need of any particular indicator, such as food insecurity, may be of great value for a provider organization. Such information could prompt the provider to develop food supply programs such as pantries, to establish effective partnerships with community and governmental agencies, or to engage in public policy advocacy. But its value as a performance measure is unclear.

In the setting of a health care organization with longitudinal responsibility for a patient or population's care, we would find great value in the use of a measure of change in the population level of a particular social need, such as food insecurity or housing instability. Such a measure has been developed in the NQF measure incubator project related to childhood food insecurity, and is being incorporated into the maintenance of certification program of the American Board of Pediatrics. However, the IQR program generally relates to the care of those with acute care hospitalizations. Although there is some responsibility for hospitals to assure appropriate follow up, as reflected in the readmission measures, addressing unmet social needs to the point at which one could see population level improvements would require more longitudinal involvement than is appropriate, and would be better served through other elements of the health care sector.

Given these concerns, we do not approve the use of this measure in the context of the Hospital IQR program at this time.

Health Care Without Harm
December 9, 2021

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and

MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission, health care has an opportunity, indeed a responsibility, to use its ethical, economic and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

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For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post November 30th: 1) More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes; 2) About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year; 3) More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness; 4) If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people; 5) Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection; 6) And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and

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entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen, President, Health Care Without Harm & Practice Greenhealth

For more information, please contact: Emma Sirois, National Director, Healthy Food in Health Care Program, esirois@hcwh.org

MS State Department of Health

This measure will not only determine what the patient's basic needs are, but it was also help in determining what programs/services are lacking in that patient's community. It will also help determine what other social determinants are playing a positive or negative role in the patient's health (mental and physical). The benefits outweigh the burden of data collection because it well help to improve the overall health in communities in identifying service gaps and referring patients to services they need. My program is in the process of screening for social determinants of health in working with expectant and parenting families. No current implementation challenges because the assessment is already built in the electronic health record database.

Phreesia

Phreesia applauds CMS's commitment to screening for social drivers of health and identifying the percent of beneficiaries who screen positive. However, there is no discussion of how the data should be collected. While the proposed IQR measure MUC2021-106 would require hospitals to train staff on health equity screenings, no measure included in the 2021 MUC List include an explicit reference to how such data should be collected. Furthermore, none of these data collection methods for social drivers or those in the equity domain specify the crucial importance of self-reported data from patients.

Self-reported data is fundamental to achieving higher quality care and an optimal patient experience. Experts agree that self-reported data is the most effective approach for data collection. Additionally, many health systems are now initiating or scaling SDOH screening, where self-reporting is crucial. Most are accomplishing this through verbal collection programs, though our experience shows that digital screening tools are by far more effective in accurately capturing patients' demographic and social needs information.

In general, failing to effectively capture patient demographic and social needs information has the potential to erode trust in the healthcare system among minority groups whose trust is already significantly low. However, when given the opportunity to input their own demographic data, we have found that patients are able to accurately provide key information and can play a key role in improving their own care by closing gaps in data. Phreesia encourages CMS to move providers to screening methods that include an explicit focus on patient self-reported data.

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Social Interventions Research and Evaluation Network at the University of California, San Francisco
December 9, 2021

National Quality Forum Measure Applications Partnership Dear Measure Applications Partnership Committee Members

As national leaders of the Social Interventions Research and Evaluation Network (SIREN), a center at the University of California, San Francisco dedicated to elevating and strengthening evidence related to programs and policies that can support health care systems to meaningfully deliver social care and as leading national experts in this evidence, we welcome the opportunity to comment on the social risk screening measures (MUC2021-134 and MUC2021-136) currently being considered through the MAP process.

We are excited to see federal level interest in quality measures related to social determinants of health (SDH) and social risks since these factors have been closely tied to health and health care utilization outcomes and equity. Incorporating feasible and impactful measures will help to signal the importance of assessing and addressing patients' socioeconomic risks as a critical part of a comprehensive strategy for improving care quality and outcomes.

We very much appreciate the potential advantages of increased recognition of patient-reported social risks in health care settings. Awareness of social risk may inform a range of interventions that have the potential to improve care quality, patient health, and reduce health costs. These interventions have been described in the 2019 National Academy of Sciences, Engineering, and Medicine report on Integrating Social Care into the Delivery of Health Care to Improve the Nation's Health. They include not only strategies to connect patients with social services, but also strategies to tailor or adjust medical care decision-making based on patients' social contexts and opportunities to strengthen data that informs community level investments and advocacy.

Recognizing the potential advantages of implementing quality measures in this area, we recommend moving forward with these measures with some modifications to address concerns detailed below. We also hope that this is just the first step in building out a robust set of quality metrics that measure, guide, and reward clinicians' and hospitals' work to improve patient outcomes by identifying and addressing social risks as part of high quality clinical care.

Although we support moving forward with these measures, we share below some key concerns based on our knowledge of the research evidence and our experiences as practitioners (for Drs. Gottlieb and Lindau), as well as recommendations for how to address these concerns.

6. Could social risk screening cause harm that outweighs benefit?

Although there is abundant evidence that social factors strongly shape health and health care outcomes and inequities, it is not yet clear whether social screening (assessing) without subsequent interventions (addressing) actually improves outcomes. Studies have found that many patients understand how social conditions relate to health and well-being and believe that screening in health care settings is appropriate. At the same time, patients have voiced important concerns about potential negative consequences of sharing information about social adversity in health care settings, including concerns that the information could be used against them, worsen feelings of stigma, and exacerbate real or perceived bias/discrimination. Where, how, and by whom screening is conducted and data are used will

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influence patients' experience and the quality measures. On the whole, evidence suggests benefits outweigh risks in contexts where needs are assessed in ways that are patient-centered and minimize risks for stigmatization and discrimination. In the future, an additional patient-centered and patient-reported measure might be considered about the experience of screening.

7. Are there drawbacks to having measures related to screening without measures related to acting on identified needs?

Incentivizing screening through quality measures without also incentivizing action on identified concerns may lead health care organizations to attend to assessment over intervention, which may have benefit for calculating risk-adjusted payment, but is unlikely to meaningfully change health outcomes. In a worst case scenario, screening that does not yield risk-adjustment could result in 'creaming' or strategies to limit service to individuals or communities with higher socioeconomic risk. At the same time, although several NIH-funded randomized controlled trials with a diversity of urban and rural target populations (e.g. families with hospitalized children, dementia caregivers, older people with diabetes, adults and children with cardiovascular disease risk) are ongoing, research has not yet provided clarity about what types and what intensity of actions are most likely to improve outcomes. Ideally the screening-focused QM will contribute to more innovation and evaluation in the intervention space. This learning should contribute to measure development around strategies to hold health care organizations accountable for acting on collected social data. One possibility is to consider revising the second proposed QM (#136) to reflect a measure of change in the screen positive rate.

8. Are these the right social domains to include in a social screening quality measure?

In 2014, the National Academies recommended routinely incorporating information about financial strain/insecurity in EHRs with follow up assessments conducted only as needed around basic material needs such as transportation, utilities, food, and housing. This recommendation is not reflected in the proposed measures. Though the four social risks related to socioeconomic security (food insecurity, housing instability, transportation problems, and utility security) included in the proposed measures may each be relevant to health and actionable, it may not be maximally efficient to screen for each of these until an overarching assessment of financial strain is conducted; on the other hand, unpublished data suggests that needs disclosure may be higher in response to individual topics. If these measures move forward as they are, in the future research on likelihood of disclosure should be revisited and the measures should be modified. Additional topics related to basic material needs also should be strongly considered, e.g. digital access (a topic of whose relevance to health disparities is rapidly changing), employment, legal needs, and childcare affordability/access.)

9. Interpersonal violence screening poses unique concerns and opportunities

Screening for interpersonal violence raises a number of unique concerns, including but not limited to the distinction between interpersonal violence and intimate partner violence. One consideration would be to require that if IPV is the only measure a health system is assessing, in order to meet the quality standard, they must also include at least one other driver of health measure from the list of other included domains.

10. The proposed measures would benefit from more detailed specifications.

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We would like to highlight two areas that are not clear about these measures: ○ It is our understanding that measure 136 (screening) is meant to only count beneficiaries screened for all five risks (vs. any of the five risks) and that the screening positivity measure (134) is meant to count beneficiaries with at least one of the needs (not only those who have all five). However, the way the measures are defined do not make this explicit. ○The measure definitions also do not specify whether clinicians and hospitals can use any screening tool or approach or whether there is a required set of questions or tools that should be used. Despite hoping for future standardization, we currently would recommend allowing flexibility in how different social domains are measured because since there are a variety of assessment tools already in use across the country. We recommend that these definitions be clarified as the measures move forward in the process.

Summary

In summary, based on our knowledge of the research evidence in this space, we recommend that these measures mover forward but with the following modifications:

• Clarify the definitions of the measures

• Provide guidance about how to conduct screening in a way that is patient centered, maximizes confidentiality, and minimizes risks of stigmatization and discrimination. Also consider adding measures of patient experience in the future.

• Ensure the measures provide clinicians and hospitals flexibility in the screening tools and approaches used.

In addition, in the future we recommend adding measures focused on the actions that providers and hospitals can take to improve patient outcomes based on screening information, since those actions are what will lead to benefits to beneficiaries.

We thank NQF for providing this opportunity to provide feedback about this important and growing part of high-quality patient care. Please reach out to laura.gottlieb@ucsf.edu if you have any questions about these comments.

Sincerely,

Caroline Fichtenberg, PhD, University of California, San Francisco Taressa Fraze, PhD, University of California, San Francisco Laura Gottlieb, MD, MPH, University of California, San Francisco Danielle Hessler Jones, PhD, University of California, San Francisco Stacy Lindau, MD MAPP, University of Chicago

United Way of the Mid-South

We welcome this opportunity to submit our comments related to the proposed addition of two new proposed quality measures related to social risk screening:

- Driver of Health Screening Rate: % beneficiaries 18 years and older screened for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-136)
- Driver of Health Screen Positive Rate: % beneficiaries 18 years and older who screen positive for food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety (MUC 2021-134)

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In 2016, the United Way of the Mid-South (UWMS), based in Memphis, Tennessee, launched Driving The Dream (DTD), a resilient human services ecosystem that aligns and better integrates the local human services, represented by 82 agencies, with the goal of connecting under-resourced families to an array of supportive services as well as clinical healthcare to improve their overall health and wellbeing. As an organization, we have worked deeply in this space and understand the nuances and complexities of coordinating and aligning clinical care and social services. As a former state public health commissioner and practicing physician, I personally understand firsthand the social and economic challenges families face when it comes to promoting their own health and the health of their children and other family members.

Given this experience and exposure, UWMS believes the introduction of these measures is a critical step in bridging the gap between clinical services and social services that address the socioeconomic and environmental factors, which as evidence supports contributes to 50% of a person's overall health and wellbeing. Adoption of these measures will provide standardized data that begin to provide insights into the depth and breadth of social barriers that contribute to poor health outcomes. Additionally, with the ability to disaggregate by demographic characteristics, it will make visible the social factors driving or inhibiting health, particularly for communities of color. Equipped with this data, human services providers can better direct existing resources to be responsive to gaps, while also more effectively making the case for additional services that may be needed.

While these measures are just a first step in terms of diagnosis, adoption of these measures has the potential to drive greater awareness among clinical providers regarding the interconnectivity of physical health and underlying socioeconomic conditions. That awareness has the potential to incentivize more formal partnerships between clinical care and social service providers, all with the ultimate goal of improving patient health and wellbeing.

We are in full support of the adoption of these measures, however, we do raise one potential implementation challenge, as it relates to screening. There are a number of social determinants of health screening tools that have been adopted and in use by both clinical providers as well as social service providers. Understanding if there are specific validated screening tools that must be used to screen and diagnose these conditions is a potential area for further exploration and discussion.

Should the review committee have any follow-up questions or additional discussion, we would be more than happy to further contribute insights and related guidance.

Sincerely,

Kenneth S. Robinson, M.D.

North Carolina Medical Society

NCMS is North Carolina's oldest professional organization, including nearly 12,000 members and a network of influential partners extending from county medical societies and specialty societies across the state, to the state legislature and Department of Health and Human Services (NC DHHS).

Consistent with our mission "to provide leadership in medicine by uniting, serving and representing physicians and their health care teams to enhance the health of North Carolinians," NCMS has long recognized and committed to act on the social drivers of health (SDOH), which directly impact health outcomes and health care costs.

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On this basis, NCMS strongly recommends that the Measurement Application Partnership (MAP) move forward two measures forward through the regulatory review process: Screen Positive Rate for Social Drivers of Health (MUC2021-134) and Screening for Social Drivers of Health (MUC2021-136).

NCMS's support for these measures is rooted in the recognition that the presence of SDOH fuels physician burnout, creates economic risk for physician practices under value-based payment models, and drives poor health outcomes for North Carolinians. This is especially so in COVID's wake: faced with the convergence of their patients' clinical and economic needs, front-line physicians and other health care providers have been taxed as never before.

We recognize the strong alignment between physicians and patients about the importance of addressing SDOH. Focus groups we have conducted with our partners show striking agreement among North Carolinians (across race, gender, income, political affiliation, and geography) on what they need to be healthy, with all the focus groups choosing to spend more money on food and housing than on health care. Focus groups with NCMS members echoed these findings, with 100% of participating physicians indicating that some, many, or all of their patients are affected by social conditions.

Our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in connecting patients to community resources.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and laying the foundation to invest in those community resources necessary for health.

Citations: https://www.healthaffairs.org/do/10.1377/hblog20210429.335599/full/

Reinvestment Partners

I'm writing in support of MUC2021-136. This measure represents a crucial step towards addressing racialized health disparities and meaningfully addressing social drivers of health. Our agency implements SDOH programs and feel strongly that these measures would generate important data that we would use to inform our program delivery and improve our ability to serve patients in need.

findhelp

MUC2021-134 (Driver of Health Screen Positive Rate) MUC2021-136 (Driver of Health Screening Rate)
Re: Comments for NQF public comment period on CMS MUCs

In response to the National Quality Forum (NQF) public comment period on Centers for Medicare & Medicaid Services' (CMS) measures under consideration (MUCs), please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation.

About findhelp

Founded in 2010, findhelp, a Public Benefit Corporation runs the largest social care network in the

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United States and has served more than eight million Americans. Our mission is to connect all people in need with the programs that serve them with dignity and ease. As part of fulfilling this mission, we will always maintain findhelp.org, a free and anonymous search tool for identifying free and reduced cost programs in every U.S. zip code. Our network is used by over 250 health systems, health plans, community health centers, and health departments in the United States to manage social care referrals, as well as tens of thousands of Community Based Organizations (CBOs). Findhelp's interoperable social care technology works with electronic health records (EHRs) and other platforms to help clinicians and other partners address the social needs of individuals in a seamless fashion.

Comments

Findhelp appreciates the opportunity to share feedback with NQF related to proposed quality measures specific to Social Drivers of Health (SDoH).

1. This measure recognizes social needs screening as an important clinical tool.

Recognizing the value of Social Drivers of Health (SDoH)

Screening for SDoH provides clinicians with actionable data on health-related social needs that may be impacting the whole person of their patients. Capturing SDoH risks and screening information can better inform provider organizations about the needs of their patients and communities. This information can help healthcare organizations connect patients to needed resources, prioritize partnerships with CBOs and vendors, and inform capacity planning.

For example, findhelp customer Boston Medical Center (BMC) developed the THRIVE SDoH Screening and Referral program to identify and address detrimental social factors preventing patients from thriving, such as unstable housing, food insecurity, financial instability, and other issues. Through the THRIVE screener, patients identify their social needs, and BMC staff refer them to both resources at BMC and in the community using the THRIVE Directory (powered by findhelp).

Governments at all levels make significant resources available to consumers related to their social needs. Such resources could include, but are not limited to, those used to address food insecurity, housing instability, transportation problems, utility help needs, and interpersonal safety.

Yet, a clinician's ability to support a patient is only as strong as his or her awareness of the patient's needs. Screening for food insecurity, housing instability, transportation problems, utility help needs, or interpersonal safety gives providers the opportunity to impact a patient's health in ways far beyond clinical interventions.

Unfortunately, connecting those resources to consumers who need them – including the nation's Medicare and Medicaid beneficiaries – can be challenging. We encourage CMS to make identifying social care needs and connecting these consumers to available resources a core part of their healthcare quality and health equity strategies moving ahead.

Incentivizing measurement of SDoH

In particular, we encourage CMS to adopt MUC2021-134 and MUC2021-136 into federal payment

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programs. These will be the first standard SDoH measures included in federal payment programs and will provide a starting point to incentivize healthcare providers to measure and report on patients' SDoH needs.

2. The benefits of the measure outweigh the burden of data collection and reporting.

Data collection is both valuable and feasible

We believe that not screening for SDoH represents a larger burden to providers than conducting the screenings. Not building SDoH measures into the health system increases the burden on physicians as SDoH are still part of their patients' clinical reality. As healthcare providers increasingly recognize the impact of SDoH on their patients and practices, especially in light of COVID, they have called for CMS to measure what matters.

While this screening work is happening around the country already, there is a strong need for a national standard for this process. In the absence of CMS SDoH measures, physician organizations (e.g., findhelp customers American Academy of Family Physicians and American Academy of Pediatrics) have developed ad hoc SDoH screening guidelines. More than 100 findhelp customers currently using our platform to screen patients for SDoH needs, and many more screen directly in their EHRs and care platforms.

CMS has already implemented these measures in a limited fashion, providing NQF and other stakeholders an opportunity to review the tangible impact to clinicians of undertaking the screening. The measure developer (the Physicians Foundation) submitted these SDoH measures because they are currently in use in the CMS Innovation Center's Accountable Health Communities model, where they have been effectively tested and implemented over 5 years with nearly a million CMS beneficiaries in 600 clinical sites and multiple practice settings across the country.

Interoperability of social care networks

After screening patients for SDoH needs, many healthcare provider organizations will want to facilitate the connection of their patients with needed services. To facilitate this vital next step, the technology exists to integrate social care referrals into EHRs or other platforms. Through platforms such as findhelp, healthcare systems, providers and CBOs are able to receive and exchange social care data from various sources within their own environment and systems of record.

MUC2021-134 (Driver of Health Screen Positive Rate)
MUC2021-136 (Driver of Health Screening Rate)
Re: Comments for NQF public comment period on CMS MUCs
In response to the National Quality Forum (NQF) public comment period on draft recommendations offered by the Measure Application Partnership (MAP) workgroups that convened last month, please see below comments related to MUC2021-134 and MUC2021-136 on behalf of findhelp, a Public Benefit Corporation. These comments were shared with the MAP prior to last month's meeting.

The MAP's initial recommendations related to MUC2021-134 and MUC2021-136 are a

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welcome development. Findhelp encourages the MAP to continue its support for the measures in the final recommendations to HHS.

Signify Health

To Whom It May Concern:

We appreciate the opportunity to offer comments pertaining to the referenced MUCs. By way of background Signify Health is a value-based care company that brings together a unique combination of services to reduce the costs and improve the quality of health care provided to beneficiaries of public and private health plans. We are a leading provider of technology-enabled, in-home assessments, complex care management, and SDOH services. We believe deeply that health flourishes in safe homes and connected communities. Every day, across the U.S., we deploy the nation's largest mobile network of duly licensed clinicians to support people where they are – in their homes, residential facilities, and communities. We take the time to fully understand their lives and use these insights to connect them to the medical and social care they need most.

Our comments apply to both proposed Measures.

> How would adding this measure add value? How would the measure improve patient outcomes?
>
> The proposed measures for data collection and reporting represent the first and necessary step to assessing the scope and scale of social needs for a population and understanding its true impact on health outcomes. Subsequent analyses of the resulting data can assist community-based organizations, payers, providers and policymakers in designing programs that are discrete, modifiable, meaningful, and impactful in addressing social determinants of health.
>
> Do the benefits of the measure outweigh the burden of data collection or reporting?
>
> Yes, however financial incentives will likely be necessary in order to accomplish broad data collection efforts. In order to relieve the associated burden, CMS could consider creative/innovative ways to collect the SDOH data to reduce burden on hospital and physician care teams. However, it is important to recognize the obvious: not all populations seek care in the traditional health system. If a hospital or physician is the sole data collection site, we are missing out on a significant population with unmet SDOH needs that could exacerbate a clinical condition that results in a subsequent hospital admission. To ensure more comprehensive data collection, public and private payer (Medicaid, ACA, MA, Medicare Supplement private insured) enrollment processes could be expanded and utilized to collect **standardized data**. Government grants could also be made available to organizations such as the United Way and other community-based entities that interact with community based organization to enlist their aid in collecting and submitting SDoH data.
>
> For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

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As an organization, Signify Health collects SDoH data on a limited basis. We utilize this information to design programs that improve access to community-based services and to improve health outcomes.

Are there implementation challenges?

Yes. From a technological perspective, ensuring the security and privacy of data collected as CBOs are not covered entities under HIPAA; and the absence of a standardized data set; and operationally ensuring appropriate and culturally sensitive training of staff necessary in order to build patient trust. Importantly, the need for financial support to cover the required additional resources, time and effort to comply fully.

Thank you for your consideration.

About Fresh, Inc.

Thank you for the opportunity to provide comments on the 2021-2022 Recommendations for Measures Under Consideration. We were happy to hear that CMS accepted the "Drivers of Health Screening Rate" and the "Drivers of Health Screening Positive" measures as part of the2021 CMS MUC list. We are writing now to recommend that you move those forward as part of the 2021-2022 Measure Applications Partnership (MAP) cycle. We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we up lift data, health insights, and community voice to meaningfully integrate food access in to the delivery of quality care. We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes . Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system. The Physicians Foundation (directed by 21 state and county medical societies across the country) has submitted to CMS two DOH measures focused on screening for food insecurity, housing instability, transportation, utility needs, and interpersonal safety. These measures represent the foundation for future measures focused on ensuring patients secure the resources they need to be healthy and enabling community investments required for health. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities (AHC)model. AHC has now screened ~1 million beneficiaries, with 69% of those who are navigation-eligible reporting food insecurity (the highest reported need).These DOH measures have gained significant traction and momentum in the healthcare sector. The Commonwealth Fund and the Blue Shield of California Foundation recently published a blog, focused on these measures as a crucial milestone on the path towards health equity.

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The Physicians Foundation also published a Modern Healthcare op-ed calling for the measures' adoption, given the profound impact of DOH on health outcomes and costs, as well as physician burden and burnout. Including food insecurity as a quality measure in the major federal healthcare programs(Medicare and Medicaid) via these DOH measures is a crucial prerequisite for CMS, states, or commercial payers to pay for access to healthy food, not as a pilot or initiative, but as a standard health benefit. Absent such measures, the impact of DOH will remain functionally invisible in federal healthcare policy making. Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch

Chief Program Officer

Josh Trautwein

Chief Executive Officer

Providence

This would increase the identification of patients with food insecurity, help connect them to resources and improve health and quality of life. The benefits outweigh the burden. The measure would be used for QI. The main implementation challenge is connecting patients to resources and closing the loop that the resources have been received.

Providence Health & Services Oregon

In the last decade, social determinants of health have become increasingly recognized by health care as a critical piece impacting patients' health and well-being. In fact, some sources share that as much as 70 percent of a person's health is influenced by social, economic, and physical factors like food, housing, and transportation. Offering social care screening and interventions allow clinical staff to feel more empowered to fully care for their patients, and patients to receive comprehensive care incorporating social and structural factors into their care plan, allowing clinicians to care more thoroughly for the whole person.

Further, those who experience the greatest burden of social needs, are often among the most underrepresented and marginalized, including communities of color, older adults, people with disabilities and those living in poverty. Offering and standardizing social needs screening across Medicare beneficiaries will allow us to better identify and address inequities and disparities in care among these populations. Screening all beneficiaries also removes any implicit bias within individuals and organizations, removing any assumptions of who is perceived to have social needs. This is critical because older adults especially are less likely to express social needs due to societal stigma, as well as personally held beliefs that others need the services more than them. We cannot deliver high quality care, truly caring for our patients, if we cannot identify barriers, like social needs, that may impact care plans and overall health.

While systems change is difficult, especially during the era of COVID-19, and adding more to clinicians' plate is a challenge to consider, this work is too important to the health of individuals, families, and communities overall not to act. Having participated in the Accountable Health Communities grant, and other national initiatives that include social needs screening for five years, we have seen clinical

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infrastructures to support this work significantly evolve. Most electronic health record systems now have some capacity to document social needs screening, making it easier to capture and report on the data, as well as use at point of care in care planning and care coordination. We have been able to better understand our patients' priorities, as well as challenges to managing their health, and take action to meet their needs. Based on time studies completed using both in-person and phone-based social needs administration, we have found it adds minimal time to both rooming and overall clinician staff time and documentation. Not only do frontline staff find it adds minimal time to rooming, patient encounters and documentation, but patients are often positive to the screening itself, even when they do not experience social needs themselves.

Based on our experiences, the greatest challenge to implementation and adoption is that it is not a required metric. Staff do not find the process complicated, and they believe it is important, but because this work is currently more in line with our organizational values rather than billing and reimbursement, it can be hard to prioritize over other required work. With the number of requirements expected of clinical teams, doing "optional" work can be the hardest to standardize and adopt. Clinics often prioritize the work that is required for reporting or is tied to billing. Without social care screening being a required quality measure, it is difficult to standardize across all care settings. To date, adoption has been most successful with clinical teams that have this work tied to national grant initiatives or aligning with CPC+ initiative and/or patient centered primary care medical home standards.

As an organization, identifying and addressing social needs aligns with Providence commitment both as a population health company prioritizing value-based care, but also aligns with our mission and vision of creating healthier communities and easing people's way. As a mission-driven health car system, we have recognized that social needs are critical from our founding. Our Sisters of Providence started their care 160 years ago by opening orphanages and food pantries, before building a hospital. They understood the importance of social needs impact on health and well-being, and we continue to honor their vision.

Providence is committed to being a partner in moving social needs screening forward and we thank the committee for their consideration and continued support.

America's Essential Hospitals

As noted by NQF staff in their analyses and expressed by the MAP, this measure does not guarantee a connection will be made between identification of social needs and an individualized action plan and resolution of the social need. The connection between screening and referral to social services is key in addressing social determinants of health and advancing equity measurement. The measure would benefit from updates that link it to actionable interventions by the organization and community partners. To that end, this type of measure also should account for a lack of nonhealth, community-based services in a particular geographic area that might limit a hospital's ability to meet the needs of a patient and is beyond their control. This measure should seek NQF endorsement with mitigation that focuses on the link between screen-positive rate and the ability to provide referral and community navigation. Additionally, work is needed to clarify for consumers what the positivity rate means in the context of improving health equity (e.g., is a higher or lower positivity rate desired?).

Carolina Complete Health Network, North Carolina Medical Society

As a cardiologist, health network executive and board member of the North Carolina Medical Society, I'm writing in support of MAP MUC-134 and 136. I serve as the President and Chief Medical Officer of Carolina Complete Health Network. This corporation is a first in kind joint venture between a large

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national payor, Centene Corporation, and the North Carolina Medical Society. Other investors in the enterprise include the North Carolina Community Health Center Association and individual community health centers serving the most vulnerable patients of North Carolina. This venture partners joined together to identify and address the gaps in healthcare that exist across NC by having the payor and provider work together to eliminate barriers to whole person health.

As the only provider-led entity in Medicaid Transformation in North Carolina, we hope to utilize data around the social drivers of health to create better individual care management support. However, to truly close the gaps in care quality, we need to pool this information and partner with community, municipal and state leaders in a community-based approach. The MAP MUC 136 hospital measure would allow this to be possible.

During my testimony in front of the MAP Hospital workgroup on 12/15/21, I referenced a scenario of high-risk acute myocardial infarction complicated by cardiogenic shock bringing a patient into hospital care. The treatment algorithm for this acute condition branches based on the patient's social drivers of health: having resources will save your life. There is no time to change the support available for the patient. High impact decisions, such as moving toward emergent cardiac transplant or left ventricular assist device use, are made based on social resources available to the patient at the time of the emergency.

Outside of basic clinical criteria, the social drivers of care are the deciding factor in who receives these supports. The health disparities associated with these heroic interventions, transplant and cardiac assist devices, are designed inside the current system. The care will not change unless we are able to go upstream: to assess the disparities on a longitudinal basis and build and complete an investment map for equity.

This increase in resources that could come from mapping deficits prior to emergency decisions around lifesaving care would generate capacity to turn the tide of health disparities. Patients would receive available treatments knowing that the appropriate social support exists in their hospital and surrounding communities.

While I agree that the hospital reporting might need clarifying score system for consumers (ex: hospital is located in a community at high, moderate or low probability of meeting social needs), it should not paralyze us from taking the needed action. Other reported outcomes that are heavily driven by social factors, for example acute MI, are already being released. Hospitalized patient outcomes are steeped in the social health of the patients in their communities. Let us take the bold step of recognizing and reporting this linkage for a more equitable future in healthcare.

Hennepin Healthcare

I am commenting on as a member of the MAP's Health Equity Advisory Group and the Chief Health Equity Officer for Hennepin Healthcare. I am writing to provide my personal opinion regarding measures MUC21-134 and MUC21-136. These measures directly address CMS Meaningful Measures 2.0's stated measurement gap/priority which focus on the "social and economic determinants." Of the 44 potential Medicare measures under consideration this cycle, only three are tagged to the domain of "equity" – and these two DOH measures are the only patient-level health equity or DOH measures. Addressing health equity at the patient-level is critical in making lasting equity improvements as seen in the MAP Health Equity Advisory Group's positive assessment of these measures, which are publically available for

review. I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. As a health system, it is important to be able to have access to these screening measures. I request the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. Hennepin Healthcare has a deep commitment to and experience in addressing patients' SDOH. Our population health department has partnered with community in a multitude of ways to work on SDOH. It is clear to me that that it is important not only to screen for SDOH, but examine and learn from the resulting SDOH screen positive rate data. We can't be afraid to be transparent and honest about where we truly are on the continuum. Hospitals will be able to satisfy the performance threshold by reporting the SDOH screening rate and screen positive rate to CMS. Performance is not determined based on the screen positive rate. Variability in this rate would of course depend on the institution's community context and patient population. Hospitals' reporting the screen positive rate would be important to these institutions and their patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. The objective of this first phase of federal SDOH measures is focused on collecting SDOH baseline data in a standard way to then support a data-driven approach to addressing health-related social needs and inform potential future measures. We cannot allow the perfect to be the enemy of the good in tackling the SDOH, but enable learning and improvement over time. We have to start and fail forward in this work. On this basis, I encourage the MAP Coordinating Committee to enable CMS's commitment to addressing equity by recommending MUC2021-134 and MUC2021-136 for MIPS and the IQR.

Optum

Patrick Conway, CEO, Care Solutions, Optum

Former Chief Medical Officer, Director of Center for Medicare and Medicaid Innovation, and Principal Deputy Administrator for Centers for Medicare and Medicaid Services (CMS)

Public Statement on 2021 CMS Measures Under Consideration: Drivers of Health

I applaud CMS for including the first measures specifically focused on the drivers of health (DOH) on the 2021 Measures Under Consideration (MUC) list – and the MAP for its thoughtful consideration of MUC2021-134 and MUC2021-136. These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.

I endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision. Given the well-recognized impact of DOH health outcomes and cost and, in particular, their disproportionate impact on communities of color, this represents a significant and historic milestone for our healthcare system.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. MUC21-134 (the screen positive rate) is especially important to both practicing physicians (like me) and to our patients

given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities.

What really matters to people is that health is more than medical care and that social drivers have outsized impact on health and healthcare costs. It is important to build models that care for people's physical, mental, and social needs, including home- and community-based care. To do so effectively and equitably, it is imperative to collect person-level DOH data– as essential step to improving patient outcomes, both by helping people access the resources they need to be healthy and enabling healthcare institutions to invest in and partner with communities.

Person-level DOH data is essential to quantify the health and economic implications of DOH and inform work on DOH-related billing codes, risk-adjustment, and cost benchmarks. For example, it is well-documented that a diabetic that is food insecure costs, on average, $4,500 more PMPY and has a greater risk of complications. Not knowing if a diabetic is food insecure is both an urgent safety and quality issue and a cost issue that must be understood – as well as key to understand and address health disparities.

I look to CMS to drive learning and accountability on the impact of DOH at the federal level. Inclusion of these DOH measures in regulatory programs like MIPS and the HIQRP would create an unprecedented opportunity to fuel collaboration across public and private partners, address factors that drive inequity in health outcomes, and begin to close CMS's stated measurement gap on the "social and economic determinants."

Through CMS Innovation Center models such as Accountable Health Communities and Comprehensive Primary Care Plus (CPC+), CMS has amassed years of data and learning across millions of beneficiaries and thousands of practices and clinical sites across the country – demonstrating that implementation of DOH screening can be done reliably and consistently over time. Further, use of these measures has revealed that 34% of beneficiaries screened positive for at least one health-related social need and those who screen positive are disproportionately racial/ethnic minorities.

Building on this foundation – and recognizing that it is untenable to continue to defer collecting and reporting data on those factors that drive up to 80% of health outcomes and associated costs – it is now time for the MAP to recommend that CMS include the first-ever DOH measures in a regulatory program.

Citations:

https://www.gsfb.org/wp-content/uploads/2018/08/Berkowitz-S.-A.-Basu-S.-Meigs-J.-B.-Seligman-H.-K.-Food-Insecurity-and-Health-Care.pdf

About Fresh, Inc.
January 10, 2022

To: Members of the NQF: Measure Applications Partnership

From: About Fresh, Inc.

RE: Support for Driver of Health Screening Rate (MUC2021-134)

Thank you for the opportunity to provide comments on the 2022 draft recommendations offered by the

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Measure Applications Partnership (MAP) Clinician, Hospital, and Post-Acute Care/Long-Term Care (PAC/LTC) Workgroups.

We are writing to offer our strong endorsement of the MAP Workgroup's support for the SDOH measures for MIPS. In addition, we urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the Hospital Inpatient Quality Reporting Program (HIQRP).

Publication of hospitals' screen positive rate would (1) improve healthcare transparency; (2) enable more targeted, data-driven community investments; (3) signify hospitals' familiarity/expertise regarding these issues; and (4) inform and strengthen quality improvement activities, including those addressing healthcare inequities.

We are writing on behalf of About Fresh, Inc., a Boston-based nonprofit that partners with health systems and civic leaders to get healthy food to the people who need it most. Our team builds retail and technology solutions that empower households to access healthy food, and we uplift data, health insights, and community voice to meaningfully integrate food access into the delivery of quality care.

We are submitting this letter because it is time to adopt federal standards for screening patients for the lived circumstances, such as food security and housing stability, that widely accepted research tells us drive a majority of healthcare outcomes1. Despite that research, CMS has to date taken only limited initial steps to address these DOH – such as allowing certain Medicare Advantage plans to spend chronically ill members' premiums on fresh produce and other DOH. Furthermore, despite the growing focus on DOH there are currently no standard food security or other DOH measures in any of the federal programs that determine how insurers and healthcare providers are paid. Among other consequences, the absence of standard DOH data and measures impede efforts to achieve racial equity in health outcomes. Given the disproportionate and profound impact of the DOH on people and communities of color, especially in COVID's wake, this represents a profound gap in our ability to understand and address the racial inequities in our healthcare system.

The Physicians Foundation (directed by 21 state and county medical societies across the country) has submitted to CMS two DOH measures focused on screening for food insecurity, housing instability, transportation, utility needs, and interpersonal safety. These measures represent the foundation for future measures focused on ensuring patients secure the resources they need to be healthy and enabling community investments required for health. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities (AHC) model. AHC has now screened ~1 million beneficiaries, with 69% of those who are navigation-eligible reporting food insecurity (the highest reported need).

These DOH measures have gained significant traction and momentum in the healthcare sector. The Commonwealth Fund and the Blue Shield of California Foundation recently published a blog, focused on these measures as a crucial milestone on the path towards health equity. The Physicians Foundation also published a Modern Healthcare op-ed calling for the measures' adoption, given the profound impact of DOH on health outcomes and costs, as well as physician burden and burnout.

Including food insecurity as a quality measure in the major federal healthcare programs (Medicare and Medicaid) via these DOH measures is a crucial prerequisite for CMS, states, or commercial payors to pay

for access to healthy food, not as a pilot or initiative, but as a standard health benefit. Absent such measures, the impact of DOH will remain functionally invisible in federal healthcare policymaking.

Thank you for your consideration of these comments.

Sincerely,

Adam Shyevitch, Chief Program Officer

Josh Trautwein, Chief Executive Officer

American Heart Association

AHA seeks clarification on what the intent of this measure is, given that screening for social drivers is also captured in MUC2021-136.

The AHA is concerned that hospitals and providers who serve disadvantaged populations or practice in rural or low socioeconomic status communities might be unfairly penalized by this measure. While it is important to capture and address social drivers affecting patients' health, hospitals and providers treating disproportionate numbers of these patients ultimately require additional dedicated resources to implement such interventions. This measure may be more appropriate if reported at system or regional level.

The AHA agrees with the MAP's recommendation to not support this measure for rulemaking with potential for mitigation for the IQR program. However, the AHA does not agree with the MAP's recommendation for conditional support for rulemaking for the inclusion of this measure in the MIPs program. CMS should clarify how this measure is tied to the purposes of the IQR program to capture hospital quality of care as well as the MIPs program to capture physician quality of care.

NC Medical Society

Further, NCMS further urges the MAP Coordinating Committee to support not only the SDOH screening measure, but also the SDOH screen positive rate measures for the IQR. Representing the perspective of front-line physicians in a diversity of urban and rural practice settings, we recognize that the MAP's endorsement of both these measures are crucial.

We and others would anticipate significant variability in the SDOH screen positive rate for practices (via MIPS) and hospitals (via IQR) depending on the community context and patient population – and also understand that the measure's value is in spurring physicians and institutions to collect and make visible this data visible.

This data would be invaluable in enabling public and private institutions to make strategic investments to strengthen community capacity to meet patients' health-related social needs, thereby alleviating the challenges faced by patients and the associated burden of these issues on physicians.

Indeed, our experience is that NC DHHS's requirement under Medicaid Transformation that all members be screened for food insecurity, housing instability, lack of transportation, and interpersonal violence has spurred crucial investments in the capacity necessary to address these issues. Specifically, this SDOH screening requirement spurred a public-private partnership to implement NCCARE360 – the first statewide, up to date, community resource database and closed loop referral platform, which is now live in all 100 of NC's counties – as well as investments in community health workers to support in

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connecting patients to community resources.

Finally, it would be deeply demoralizing for practicing physicians to engage their patients around these crucial issues, only to then not have their institutions make the results of this SDOH screening public – reinforcing physicians' longstanding concerns regarding measurement burden that does not translate to value for providers or their patients.

We view the proposed SDOH measures before the MAP as crucial to CMS recognizing the impact of these issues on patients and providers alike – and to laying the foundation to invest in those community resources necessary for health. We urge the MAP Coordinating Committee to evidence its commitment to addressing equity and to addressing the realities of patients' lives and their impact on physicians by recommending to CMS both MUC2021-134 and MUC2021-136 for MIPS and the IQR.

Boston Children's Hospital
Dr. Kathleen Conroy

Public Statement on 2021 CMS Measures Under Consideration:

MUC21-134 and MUC21-136

As a practicing pediatrician and the Clinical Chief of Boston Children's Hospital's primary care center, with deep experience in implementing screening for social determinants of health, I offer my enthusiastic support for the decision of MAP Clinician Workgroup to support both MUC2021-134 and MUC2021-136. Further, I encourage the MAP Coordinating Committee to recommend both these measures for Hospital Inpatient Quality Reporting Program.

At my own practice, which serves 22,000 children, we have been formally and universally screening the adult caregivers of these children for SDOH for over a decade – along with many of our peer institutions across the country. Like many clinicians, we adopted this practice because of the overwhelming evidence that screening is both acceptable to families and helps facilitate connections to needed social resources, like housing programs or SNAP benefits, which themselves are associated with positive impacts on child and adult health and well-being. Just like screening for depression and anxiety, screening for and addressing social determinants of heath has become a standard part of our clinical program.

More recently, in 2018, the Massachusetts Medicaid program introduced two quality measures through its current 1115 waiver that are nearly identical to MUC21-134 and 136. Although we were already screening, the need to report the percent of our patients screening positive for various needs across our clinic and our entire ACO population allowed us to understand two things: (1) who in our population was most likely to have needs and how these needs are changing over time and (2) whether our systems of screening and response were unintentionally inequitable.

This knowledge has become the foundation for both disparities-focused quality improvement programs and also the impetus for the creation of new community partnerships to be better address needs of certain populations. For this reason, I would argue that both MUC21-134 and 136 are crucial.

To those who may be surprised that these measures do not require navigation to resources, I would

offer that Massachusetts similarly did not initially require navigation to resources. This has allowed healthcare organizations the opportunity to build their response systems after initially understanding their families' needs, and it has allowed them time to build data systems to record the social needs responses delivered to families. In my clinic, for example, we recognized that we were under-documenting our work with families once needs were identified and have improved this in anticipation of needing to ultimately report our response to positive screens.

Likewise, it is important that these proposed initial social determinants of measures specify the five target social determinants of health domains (linked to the Accountable Health Communities model), but do not require the use of a specific screening tool, enabling providers to exercise flexibility in this regard.

Given my own extensive, on-the-ground experience functionally implementing these specific SDOH measures – and recognizing that it is untenable for our healthcare system to continue to defer collecting and reporting data on food insecurity, housing instability, and other social factors that drive up to 80% of health outcomes and associated costs – I strongly recommend that the Coordinating Committee recommend MUC21-134 and 136 to CMS for implementation in MIPS and the HIQRP.

Texas Medical Association

TEXAS MEDICAL ASSOCIATION 401 WEST 15TH STREET AUSTIN, TEXAS 78701-1680 (512)370-1300 FAX (512)370-1693 WWW.TEXMED.ORG

January 13, 2022

The Honorable Chiquita Brooks-LaSure

Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

200 Independence Ave.

Washington, DC 20201

RE: Texas physicians continue strong support for measures that drive health quality (MUC2021-134 and

MUC2021-136)

Dear Administrator Brooks-LaSure:
On behalf of our more than 56,000 Texas physician and medical student members, the Texas Medical Association (TMA) writes with our further support for measures that drive health quality. In addition, we continue to support the National Quality Forum's Measure Applications Partnership (MAP) process.
At TMA, we recognize that social determinants of health (SDOH) have a profound impact on patients and the physicians who care for them, especially in the wake of COVID-19. The two measures MUC2021-134 and MUC2021-136 signal that the Centers for Medicare & Medicaid Services (CMS) has begun to recognize and address the significant impact that social determinants of health have on health disparities, outcomes, and costs. Additionally, social drivers impact both physician well-being and the

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economics of clinical practice.

With this context, we register our strong endorsement and support of the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

TMA strongly urges the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital Inpatient Quality Reporting Program (HIQRP) – recognizing that both these measures are crucial.

It is crucial to note that, in the absence of any standard SDOH measures, physicians are functionally held clinically and financially responsible because patients with greater social risk – which is not currently measured or included in risk-adjusted cost benchmarks for alternative payment models – are associated with higher health care costs. Obscuring the results of the social needs screening – by rejecting MUC21-136 –would make invisible crucial drivers of health outcomes, costs, and disparities, and impede appropriate investments in the community resources necessary to improve our patients' health.
For example, via the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities model – which extensively tested these specific proposed SDOH measures in more than one million beneficiaries in both hospital inpatient and emergency department settings and primary care practices– CMS learned that 34% of beneficiaries screened positive for a health-related social need, and among that group, racial and ethnic minorities were over-represented. Further, it identified that food insecurity was the most commonly reported health-related social need among navigation-eligible beneficiaries, followed by housing and transportation. It is this kind of data that is imperative to understand the needs of patients and communities, as well as the underlying factors driving variation in health care costs. For example, numerous studies have now quantified
the impact of patients' social risk on physician performance scores through the Merit-Based Incentive Payment System (MIPS) and its impact on the geographic variation in Medicare spending (37.7% when including both direct and indirect associations).

Recognizing this, physicians in Texas already are working to effectively identify and address their patients' health-related social needs. We do so recognizing that screening patients for social determinants of health is, as one of our colleagues recently observed, "just like when you use a screening tool or test to diagnose a medical condition. The diagnosis and the plan to address the problem can be enhanced by understanding some of the social needs, i.e., social determinants, that can get in the way, or may have already gotten in the way of making this person as healthy as they could be.

This is not about ascribing fault as much as it is identifying factors that should be considered or addressed." TMA strongly supports that the MAP Coordinating Committee recommend both MUC21-134 and MUC21-136 for both MIPS and HIQRP, recognizing that doing is essential to advance CMS' stated commitment to equity as well as to enacting measures that matter to patients and physicians.
We appreciate the opportunity to comment on this matter. If you have any questions, please do not hesitate to contact Karen Batory, MPA, TMA vice president of population health and medical education, at Karen.Batory@texmed.org.
Sincerely,
E. Linda Villarreal, MD

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President
Texas Medical Association

Humana, Inc.
January 13, 2022

National Quality Forum

Measure Application Partnership

1099 14th St. NW, Suite 500

Washington, DC 20005

RE: 2021-2022 Recommendations for Measures Under Consideration

To Whom It May Concern:

This letter is in response to the National Quality Forum's Measure Application Partnership (MAP) comment opportunity on the 2021-2022 Recommendations for Measures Under Consideration. Humana applauds CMS for including the first measures focused on the social drivers of health (SDOH) on the Measures Under Consideration list, MUC21-134 and MUC21-136. These SDOH measures directly address the Centers for Medicare and Medicaid Services (CMS) Meaningful Measures 2.0's stated measurement gap/priority focused on the "social and economic determinants."

Humana Inc., headquartered in Louisville, Kentucky, is a leading health care company that offers a wide range of insurance products and health and wellness services that incorporate an integrated approach to lifelong well-being. As one of the nation's top contractors for Medicare Advantage (MA) with approximately 4.4 million members and Medicare Prescription Drug Plans (PDPs) with approximately 3.9 million members, we are distinguished by our nearly 35-year, long-standing, comprehensive commitment to Medicare beneficiaries across the United States. These beneficiaries – a large proportion of whom depend upon the Medicare Advantage program as their safety net and many in underserved areas – receive integrated, coordinated, quality, and affordable care through our plans.

MUC21-134 and MUC21-136

In COVID-19's wake, food insecurity, housing instability, and other SDOH have reached unprecedented levels and revealed massive racial disparities. Yet, despite the well-documented impact of SDOH on health outcomes and costs and their disproportionate impact on communities of color, there are still no SDOH measures in the Quality Payment Program (or other CMS quality and payment programs), which is only more significant in light of COVID and HHS/CMS's commitment to equity.

We recognize that of the 44 potential Medicare measures under consideration by CMS this cycle, only three are tagged to the domain of "equity," including these two measures. We also note the MAP Health Equity Advisory Group's positive assessment of these measures.

With this context, we write to endorse the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 for inclusion in the Merit-based Incentive Payment System (MIPS) and encourage the MAP Coordinating Committee to accept this decision. We believe this is a historic milestone for our healthcare system.

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Screen Positive Rate for Social Drivers of Health

Humana further strongly urges the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital Inpatient Quality Reporting Program (HIQRP). We believe it is important to include both measures because, together, they will make visible the impact of health-related social needs on patients.

MUC21-134 (the screen positive rate) is especially important in that it creates the opportunity to reveal and address disparities, both with respect to SDOH and their impact on health outcomes and costs. This anticipated variability in screen positive rates – including SDOH disproportionate impact on diverse communities and communities of color – would be important in enabling public and private institutions to direct investments in communities.

From Humana's perspective, we have long been committed to addressing the impact of health-related social needs on our members and addressing SDOH in communities across the country. In 2020 alone, we completed 6.2 million SDOH screenings; this data and the overall SDOH screen positive rates of our members, which we have made public, has been invaluable in enabling us to partner effectively with dozens of other organizations in addressing needs among our members and in communities, including appropriately targeting our investments to address these issues.

While we agree that taking action on the result of the screening is important – and is something Humana itself is committed to doing – we recognize that the objective of this first phase of federal SDOH measures is focused on collecting standardized SDOH baseline data to support a data-driven approach to addressing these health-related social needs and inform potential future measures. In this regard, we believe – and have learned through our experience at Humana – that we cannot allow the perfect to be the enemy of the good in tackling the SDOH, but instead must prioritize learning and improvement over time.

On this basis, we encourage the MAP Coordinating Committee to enable CMS's commitment to addressing equity by recommending MUC2021-134 and MUC2021-136 for MIPS and the HIQRP.

We value this opportunity to provide comments and are pleased to answer any questions you may have. We hope that you consider our comments as constructive feedback aimed at ensuring that we continue to advance our shared goals of improving the delivery of coverage and services to Medicare beneficiaries and addressing health disparities, focused on improving the total health care experience of all Medicare beneficiaries.

Sincerely,

J. Nwando Olayiwola, MD, MPH, FAAFP

Chief Health Equity Officer & Senior Vice President

Humana, Inc.

Andrew Renda, MD, MPH

VP | Bold Goal & Population Health Strategy

Humana, Inc.

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Johnson & Johnson

Johnson & Johnson disagrees with the recommendation of the Hospital Workgroup and suggests that MAP's recommendation be brought into alignment with the Clinician Workgroup's review of the measure. The reliability and validity concerns expressed by the Workgroup should be left for deliberation inside of NQF endorsement committees. It is important to routinely screen patients for social drivers of health that may impact access to diagnostics, treatment, and supportive care services. We appreciate the flexibility the measure offers for screening approaches but support future standardization of tools to ensure that providers have clear guidance and best practices for identifying patients at risk. While clinician and practice-level screening is important, it will not capture patients whose social drivers prevent them from accessing care entirely. Transportation, health literacy, education, and living situation, among other factors, significantly impair individuals from accessing care in the first place. We therefore encourage CMS and NQF to think about measures at other levels of analysis (e.g., surveillance measures) to understand how these social drivers impact Medicare populations more broadly.

American Medical Association

The American Medical Association (AMA) supports the current recommendation for this measure but asks that an additional mitigation be added. Specifically, that the factors included in the measure are aligned with the work of the Health Level 7 Gravity Project and the United States Core Data for Interoperability (USCDI). We believe that this addition is consistent with the Hospital Workgroup's discussion.

Blue Shield of California Foundation

Blue Shield of California Foundation strongly supports MUC21-136, Screening for Social Drivers of Health, and MUC21-134, Screen Positive Rate for Social Drivers of Health, and urges the MAP Coordinating Committee to support both measures for rulemaking and inclusion in both MIPS and the Hospital IQR.

Nearly 90 percent of hospitals and health systems across the country are already conducting Driver of Health (DoH) screening to identify patients' unmet social needs, according to one recent study, including via a number of CMMI models, but without the benefit of any formal quality measures, guidance, or tools from CMS.

As evidenced in the momentum for these measures across the health sector, it is imperative that we begin to implement DoH measures into federal payment programs, especially in the wake of the deep health inequities revealed by our response to COVID. With this context, we applaud the MAP for its thoughtful deliberations on MUC21-134 and MUC21-136, two of only three equity measures under consideration by the MAP and CMS this year.

In particular, we applaud the leadership of the MAP Clinician Workgroup in supporting both MUC21-134 and MUC21-136, and applaud the Hospital Workgroup in likewise supporting MUC21-136 – and encourage the MAP Coordinating Committee to endorse these decisions. We are troubled, however, by the MAP Hospital Workgroup's vote on MUC21-134: "do not support with potential for mitigation."

First, the NQF MAP summary of the Workgroup's recommendation states that the "measure has not

been evaluated for reliability or validity." Yet NQF's own preliminary analysis cites documentation that the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of reliability and validity.

Second, the Hospital Workgroup "expressed concern that the positive rate may be challenging for consumers to interpret when publicly reported." Through the lens of a commitment to equity, we find it remarkable that the Workgroup has determined that consumers would be unable to exercise their own judgment in interpreting important data about the degree to which their fellow consumers are impacted by social drivers of health. We believe a hospital's reporting of the screen positive rate will be important to patients for a number of reasons, including: (1) providing transparency; (2) enabling the targeting of hospital and community investments based on the social needs shown by the data; (3) signifying the hospital's understanding of the social drivers of health among its patient population; and (4) providing data for targeting quality improvement activities, including highlighting and addressing disparities in the social drivers of health for patients.

Finally, we recognize that the measures are focused on screening beneficiaries for drivers of health, and do not require an action plan. At the same time, we believe these measures represent an important starting point for collecting DoH baseline data in a standard way to then support a data-driven approach to addressing these social drivers. We note that CMS's own CPC+ model demonstrates clinicians' appetite to engage in this screening and act on these results, even when not required: 86 percent of Track 1 practices reported that they screened patients for health-related social needs (though not required to do so) and 93 percent of physicians in those practices reported that they acted on those screening results.

The introduction of these first DoH measures into core federal payment programs would be significant in its own right: making visible, when stratified by race and ethnicity, the social factors driving or inhibiting health, particularly for communities of color, including food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Only when these factors are brought to light and measured in a standardized way will we be able to align our collective resources and take action to achieve equitable health outcomes for all. To achieve this goal, we strongly encourage the MAP Coordinating Committee to recommend to CMS MUC2021-134 and MUC2021-136 for both MIPS and the IQR.

Health Care Without Harm
January 11, 2022

On behalf of Health Care Without Harm, which maintains a hospital member network of over 1,400 hospitals across the country, we strongly support the National Quality Forum Measure Applications Program (NQF MAP) working groups in recommending the following two Drivers of Health (DOH) measures under consideration:

MUC 2021-136; Driver of Health Screening Rate, and

MUC 2021-134; Driver of Health Screen Positive Rate

Health Care Without Harm is founded on the belief that: As the only sector with healing as its mission,

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health care has an opportunity, indeed a responsibility, to use its ethical, economic and political influence to create ecologically sustainable, equitable and healthy communities. Founded over 25 years ago, Health Care Without Harm seeks to transform health care worldwide so that it reduces its environmental footprint, becomes a community anchor for sustainability and a leader in the global movement for environmental health and justice. We conduct research, model strategic interventions and provide guidance and resources to spread and accelerate best practice in the field – with programs focused on climate and health, safer chemicals, and healthy food.

Health Care Without Harm has long recognized the impact that DOH have had on increasing rates of poor health outcomes, chronic disease and death. Climate change, the COVID-19 pandemic and increasing economic and social inequities in our communities that are the result of decades of systemic racism only serve to exacerbate the situation.

For example, some sobering statistics regarding diet-related diseases and how food insecurity is impacting our nation's health, published in The Washington Post (November 30, 2021) :

- More than 100 million Americans — nearly half of all adults — suffer from diabetes or prediabetes.
- About 122 million Americans have cardiovascular disease, which kills roughly 840,000 people each year.
- More Americans are sick or suffer from major medical conditions than are healthy, and much of this is related to diet-related illness.
- If you are a Black person, those numbers mean you probably will have an even worse outcome. 49.6 percent of Black adults are considered overweight if not obese. Black people are also 60 percent more likely to be diagnosed with diabetes than White people.
- Americans who suffer from diet-related conditions such as heart disease, diabetes, cancer, and obesity are 12 times as likely to die after a COVID infection.
- And in 2020, the year COVID-19 hit the United States, African Americans were disproportionately impacted by the virus, many due to those same underlying diseases of obesity and diabetes. In total, Black people experienced a 2.9 year decrease in life expectancy, causing the Black-White life expectancy gap to widen from 3.6 to 5 years. In a single year.

Statistics similarly alarming can be found regarding the health impacts of poor indoor air quality, air pollution, climate change, poor access to public transportation or living close to a freeway or port, housing instability, and exposure to toxic chemicals in the air, land and water. And they are disproportionately affecting under-resourced communities of color. The frightening question is, how big and bad do the numbers have to get? What is the final tipping point before the federal government will declare a state of public health emergency and prioritize addressing the DOH with a systemic strategy? A coordinated, aligned national standards measurement process to screen for DOH as part of basic primary health care is absolutely critical to moving forward, and these two measures are a positive start.

The Physicians Foundation, which is directed by 21 state and county medical societies across the country, submitted these first-ever measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety, including intimate partner violence. Their adoption would represent a crucial milestone as the first standardized federal measures to assess social need in the history of the U.S. health care system.

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Despite the well-documented impact of DOH on health outcomes and costs and their impact on people of color, there are still no approved, standardized DOH measures in any Centers for Medicare and Medicaid Services' (CMS) programs. The impact of DOH interventions remain fairly invisible in federal health care policymaking, and the absence of standard DOH data or measures impedes efforts to achieve racial equity in health outcomes, given their profound impact on people and communities of color, especially in COVID's wake.

In enacting these first federal DOH measures, CMS could send a powerful signal to the health care sector and the communities they serve that there should be acknowledgement of how DOH impact peoples' health outcomes and an intention to address them in a coordinated strategy across the country. These initial DOH measures for screening could lay the foundation for additional measures focused on navigating beneficiaries to resources and connecting beneficiaries to the resources they need to be healthy.

We urge the Coordinating Committee to recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. And by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) engaging community partners to tackle these issues.

When addressing issues such as food insecurity, housing instability, climate change, lack of transportation, and exposure to toxics in our air, land and water, we cannot settle on solving for acute, short-term health impacts alone. We must devise long term solutions for these long term and entrenched challenges that require equitable investment and attention. Our collective environmental and economic health need to be prioritized, with regenerative systems that are protective of our environmental health and natural resources, and substantial investment in fair labor practices and living wage mandates.

It is our hope that CMS will do the right thing and approve these measures, creating a federal, standardized system to incorporate DOH factors into primary health care and begin to set the stage for long term effective intervention.

Signed by:

Gary Cohen

President, Health Care Without Harm & Practice Greenhealth

www.noharm.org

Contact: Emma Sirois, National Director, Healthy Food in Health Care Program, esirois@hcwh.org

Cambridge Health Alliance

As a family medicine physician practicing at the Cambridge Health Alliance in Cambridge, Massachusetts, I applaud CMS for considering the first measures specifically focused on the social drivers of health (MUC2021-134 and MUC2021-136) and the NQF MAP for its consideration of these measures.

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These measures are particularly significant given that of all the potential Medicare measures under consideration by CMS this cycle, these are the only patient-level health equity or DOH measures.

For the past decade, I have been deeply involved in efforts by CHA and other health systems and community health centers in MA to screen patients for the social drivers of health. I have extensive experience implementing SDOH screening and navigation protocols at scale and have published on the resulting findings.

It is clear that food insecurity, for example, is not just a social factor, but a clinical co-morbidity that impacts quality care and drives health disparities.

Given COVID, SDOH screening has become only more critical to support our patients and to mitigate the frustration and burnout among primary care providers. Yet, we now do so without the benefit of any SDOH measures in any federal payment program, including MIPS. It is untenable for our federal payment programs to continue to exclude those factors that we know drive 80% of health outcomes in our patient populations.

At CHA, my colleagues and I have screened thousands of patients in over a dozen primary care sites across our healthcare system; in doing so, we found that nearly 30% of our patients screen positive for food insecurity.

Had we not collected and share this data, we could not have developed effective strategies and community partnerships to address these challenges with our patients. In particular, this crucial data about our patient population – exactly the kind of foundational data that these SDOH measures will provide – then allowed us to design an electronic active referral to a community-based organization.

One question that has come up is whether these measures will, hypothetically, incentivize providers to treat fewer patients with social needs or to move way and care wealthier patients. But from the perspective of a physician who – like thousands of others across the country – is committed to serving patient populations that often face these challenges, these first-ever federal SDOH measures are essential to recognize practices (like mine) that are tackling these issues.

With this, I enthusiastically support the MAP Clinician Workgroup's decision to recommend both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further strongly urge the MAP Coordinating Committee to support the SDOH screening and the screen positive rate measures for the IQR, recognizing that both these measures are crucial. The latter measure is especially important to practicing physicians and to our patients, given the imperative of transparency in reporting and the opportunity for such data to enable quality improvement activities, including addressing disparities, as we have done at CHA.

Hogg Foundation for Mental Health

This is an important measure to consider to finally start including the impact of the social determinants in the ambulatory setting. The data generated will provide greater understanding and lead to more informed interventions by the clinical team and for social interventions. Extremely important for interdisciplinary team-based care. The benefits do outweigh the cost of data collection, especially when one considers this measures potential to track and monitor the quality of holistic health care outcomes.

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The challenge will be for all providers and team members to include and utilize this measure appropriately.

The Physicians Foundation

In submitting these comments, the Physicians Foundation does so not only as the measure developer for MUC2021-134 and MUC2021-134, but also an organization that takes its the direction of physicians from 21 state and county medical societies across the country.

In particular, we offer these comments from the perspective of practicing primary care physicians and specialists across the country. Every day, we encounter patients in our practices who show the physical toll of skipping meals to feed their children. Who have made impossible tradeoffs between refilling their heart medicine or buying food. Who carry the stress of spending weeks trying – and failing – to find a job, as bills pile up and they fear losing their home, as the rent or mortgage goes unpaid.

As our patients struggle to manage these risks in their day-to-day lives, we physicians bear the economic and psychic risk associated with these unaddressed social drivers of health. It is well-documented that these factors lead to physician burnout and effectively penalize physicians caring for affected patients via lower MIPS scores. A recent study in JAMA found that SDOH were associated with 37.7% of variation in price-adjusted Medicare per beneficiary spending between counties in the highest and lowest quintiles of spending in 2017. Yet even with an ongoing pandemic that has painfully brought these issues to the fore, SDOH are still not accounted for in geographic risk-adjustment or cost benchmarks.

We put forward these two first-ever SDOH measures (and the only patient-level equity measures this review cycle) because it is untenable – to patients and their physicians – for these challenges to be much-discussed in articles, speeches, and white papers, yet functionally invisible in our healthcare system's quality and payment frameworks.

We must start somewhere, and we must start now. Via CMS's own Accountable Health Communities model, the proposed SDOH screening measures – MUC21-134 and MUC21-136 – have been tested at scale over five years with 1M+ beneficiaries in over 600 clinical sites – with 40% of the screenings in hospital inpatient or ED settings and 54% in primary care practices. As documented in the AHC evaluation, these measures reliably identify: (1) beneficiaries with 1+ health-related social needs; (2) high cost/high use beneficiaries; and (3) racial/ethnic disparities.

Further, as well-documented in the NQF MAP's preliminary analysis, the screening tools and items used in the testing process to generate the data for both measures have been psychometrically evaluated and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity (see sample citation below).

We appreciate the MAP's thoughtful and deliberate consideration of MUC21-134 and 136 and note the support for these measures across the Health Equity and Rural Health, Advisory Groups and Clinician Workgroup – and we strongly urge the Coordinating Committee to recognize this by accepting the recommendations of the Clinician Workgroup with respect to MIPS. It is especially important that those clinical practices that wish to collect and report on these SDOH measures have these important efforts recognized through the MIPS program.

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We also urge the Coordinating Committee to accept the Hospital Workgroup's recommendation to offer conditional support to MUC21-134. We likewise recognize that Workgroup's questions regarding how CMS and consumers could or should interpret the screen positive rate results required by MUC21-136.

As CMS itself made clear in this discussion, hospitals would satisfy the performance threshold by reporting the screening rate and screen positive rate to CMS for patients who are 18 years or older at the time of admission. Performance is not determined based on the result of the screen positive rate; there is no requirement to demonstrate a rate reduction over time. Variability in this rate would, of course, depend on the institution's community context and patient population.

Hospitals' reporting of the SDOH screen positive rate is valuable to consumers for a number of reasons, including (1) providing transparency of data the institution has collected from those and other consumers who received care at the institution; (2) enabling public and private institutions – including the hospitals themselves – to target community investments based on data consumers provided; (3) allowing consumers to identify which hospitals have familiarity with and expertise in addressing these issues; and (4) enabling quality improvement activities, including making visible variation in health outcomes and costs potentially attributable to the prevalence of these underlying drivers of health and addressing disparities.

We agree that it is important to bridge patients who screen positive for health-related social needs to community navigation services and/or ensure there is an individualized action plan in place for these needs to be addressed. However, physicians are well aware that this is complex and resource-intensive work, which is dependent on the quality of the community resource landscape where their practices and/or health systems are located and their patients live. Hence, the objective of this first phase is focused on collecting DOH baseline data in a standard way to then support a data-driven approach to addressing these health-related social needs, including potential future measures focused on success in navigating patients to the resources they need to be healthy. To establish an SDOH navigation measure in the absence of practices and hospitals reporting baseline SDOH screening data is inadvisable.

Moreover, it must also be stressed that the validation of any screening tool used to collect data supporting a measure must include the result of the screen. Should the Coordinating Committee recommend the screening rate measure but reject the screen positive rate measure, it will impair the ability of CMS, the measure steward, and program participants to conduct additional validation of the screening rate measure post-implementation and over time.

We expect, and hope that, over time, these SDOH measures can and will be improved – and additional associated measures developed – with the benefit of the input of physicians, other healthcare providers, and health systems across the country and the data generated by these measures.

We also recognize, however, that given the profound challenges that COVID has wreaked on patients, physicians, and our healthcare system writ large – and the commitment to equity and the reduction in health disparities that CMS and healthcare institutions across the country have declared – that time is of the essence in enacting these first-ever SDOH measures (and the only patient-level equity or SDOH measures under review this cycle). We therefore strongly urge that the Coordinating Committee recommend to CMS MUC21-134 and MUC21-136 for both MIPS and the IQR.

Citation: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/

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Vizient, Inc.

We commend NQF and CMS for efforts to prioritize health equity and for developing a measure that attempts to measure the impact of social drivers of health for patients. Vizient, Inc. is the nation's largest health care performance improvement company and serves a diverse membership of hospitals and other non-acute health care service providers in rural America, including independent community hospitals, critical access hospitals, rural health clinics and other non-acute providers. Vizient and its members recognize the critical need to addressing social drivers of health for each patient to ensure equitable health outcomes for all patients in our nation, and wholly support efforts to increase screening all patients for social drivers of health.

Our primary concern with MUC2021-134 is the lack of standardization for data collection for this metric. The current measure does not include specification for defining either the denominator (i.e., patients to be screened) or the numerator (i.e., what constitutes a positive screen). Without clear definitions of who to screen or what constitutes a positive screen, it will be difficult to meaningfully interpret the data collected or benchmark. Without these definitions, the publicly reported data could be misleading.

In addition, MUC2021-134 does not account for differences by geography. Vizient's analyses have shown significant variation in community need across large geographic areas as well as within local markets at the zip code level. Similar to the need for definitions, without accommodations for geographic variation, interpretation of these data when reported publicly could be misleading. Vizient notes that accommodations for geographic variation could be achieved through benchmarking using an index of local obstacles to care (e.g., Vizient Vulnerability Index, more information is available at: https://newsroom.vizientinc.com/leveraging-vizients-clinical-data-base-newly-created-index-supports-hospitals-health-equity-efforts.htm). Vizient has recently reviewed several state and national indices intended to help provide benchmarks for community need, and found an opportunity to expand upon these indices to ensure standardization across the country and also tie community need to hospital performance. Vizient is willing to work with NQF and CMS to leverage our analysis or conduct a similar analysis to evaluate current indices and address gaps before selecting a standard. Vizient notes our concern that data lacking such accommodations could potentially disadvantage hospitals or providers with higher levels of community need.

Collectively, the aforementioned issues related to data collection standardization and geographic differences also limit the utility of the collected data for future analysis; namely specific measures to promote addressing social drivers of health for patients.

Before finalizing this measure, we recommend CMS provide clear standards for defining the target populations for screening as well as clearly defining a positive screen for the target population. These definitions should be grounded in currently available data and leverage tested indices to provide a standard approach, especially for correcting for geographic variation. Without these definitions and corrections, the likelihood of negatively impacting both reporting hospitals and providers as well as patients is high.

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Association of American Medical Colleges (AAMC)

The AAMC recommends that the MAP revise its recommendation to do not support for rulemaking. We are concerned that in addition to the need for NQF review and endorsement, this measure simply is inappropriate for the IQR Program, which is "intended to equip consumers with quality-of-care information to make more informed decisions about healthcare options." This measure does not assess quality of care delivered by the hospital, but rather the percentage of patients served by that hospital who report a health-related social need. It is unclear how patients or providers can interpret that information to make informed decisions about their care. For example, is a lower rate better? This lack of clarity could result in significant unintended consequences, namely greater divergence between hospitals that treat patients who screen positive for health-related social needs and those that do not. Additionally, it's unclear how an overall positivity rate is useful for driving quality improvement – it doesn't direct attention to specific health-related socials needs of patients and thus does not provide information to inform actionable interventions.

Kaiser Permanente (retired); NASEM Roundtable on Population Health Improvement (co-chair); Secretary, Board of Directors, CDC Foundation; Trustee, Blue Shield of CA Foundation

We know that racial inequities in health outcomes persist because remedies often focus only on reducing disparities in clinical care and not on the drivers of health. Some have suggested it is not feasible to do this at scale in the clinical setting. Two decades of work by Kaiser Permanente has demonstrated that this is not only feasible and effective, but embraced by clinicians and patients when the right tools and processes are put in place. Kaiser Permanente built its SDOH screening and followup on a clinical prevention platform that had already included, for example, screening for tobacco use, physical activity and domestic violence. As Kaiser Permanente's extensive community health investments deepened its understanding of how factors like food and housing security and personal safety shaped the health of individuals and entire communities, the system introduced more formal screening, referral and community partnerships to realize the full potential of identifying and addressing SDOH.

Now, many healthcare delivery systems across the country have committed to screen and address their patients' social needs – but are doing so without the benefit of any SDOH measures in any federal payment model, including Medicare or Medicaid. Indeed, a recent study in JAMA found that 24% of hospitals are already screening for all 5 SDOH domains (food, housing, transportation, utilities, and interpersonal safety) and 92% are screening for one or more of the 5 SDOH domains specified in the measures. At the same, a 2020 study conducted at Kaiser Permanente found that patients were in favor of health systems asking about social needs (85%) and helping to address those needs (88%).

With this context, I write to offer my support for the MAP Clinician Workgroup's decision to support both MUC2021-134 and MUC2021-136 and encourage the MAP Coordinating Committee to accept this decision.

I further urge the MAP Coordinating Committee to support both MUC21-134 and MUC21-136 for the Hospital IQR, recognizing that, together, these measures reveal the impact of health-related social needs on patients and the opportunities to realign resources to invest where they are needed most.

It is important to note that both the SDOH measures under review today are critical to make visible the impact of these issues on the lives of patients and the disparities they spur. Given the disproportionate impact of SDOH on people of color, equity requires us to recognize providers for screening their patients

and reporting the screen positive rate, to elucidate racial/ethnic disparities in DOH that, in turn, fuel disparities in health outcomes.

One key lesson we've learned in this work over the past twenty years is that we cannot allow the perfect to be the enemy of the good. The MAP Coordinating Committee has a crucial opportunity to support moving the first-ever SDOH measures into practice to enable learning and improvement over time. The data collected and learning from these foundational SDOH measures will be critical to improve the measures over time and to be thoughtful in developing the next set of measures focused on ensuring patients get the resources they need.

Finally, we are cognizant that there only 3 measures tagged to the domain of "equity" and these are the only patient-level SDOH measures or equity measures under review, making it all the more imperative that the MAP Coordinating Committee recommend them. In the wake of COVID, it is simply unacceptable to go yet another year without any federal payment program measures that recognize the profound impact of SDOH on the lives of our patients.

Citation: https://jamanetwork.com/journals/jamanetworkopen/article-abstract/2751390

https://pubmed.ncbi.nlm.nih.gov/31898132/

American Hospital Association

The AHA agrees with the MAP's recommendation of Do Not Support with Potential for Mitigation. We echo all of our logistical and conceptual concerns listed for MUC21-136, Screening for Social Drivers of Health, and offer additional considerations below.

In its description, the measure score interpretation is listed as "lower score is better," suggesting that a smaller percentage of adults who screen positive for certain drivers indicates better performance. This reading is problematic for several reasons. One could reason that a higher score is actually an indicator of better performance and successful application of the screening tool, as it would indicate that more of these social drivers of health are being identified and potentially addressed. One could also reason that performance on this measure is only an indicator of the characteristics of the patient population served by the hospital; a lower score could simply mean that the hospital is located in an area with high average income, better public transportation, and more accessible nutrition. None of those characteristics is related to quality of care.

CMS does not provide data showing clear causal relationship between quality of care and the proportion of patients with higher social risk scores on this measure. While patient outcomes are often poorer for patients who demonstrate these social drivers of health, nothing in this measure's description makes the connection between a positive screen for a social driver of health and actual utilization—or even availability—of services to address patients' social needs.

We reiterate that identifying social drivers of health is vital, and that we as hospitals, health systems, and society as a whole must do better to address disparities in health outcomes and the underlying social pressures that exacerbate these disparities. However, using this measure as currently specific in the inpatient setting is not the way to make progress on this goal.

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KAREN L SMITH MD PA

Patient access to tertiary care systems is driven by many factors but a common reason is due to lack of a designated primary care provider. The data obtained during these encounters will fill a void for when no other mechanism exists to capture this information.

The measure is improved for capturing the true existence of social drivers when all access points are part of the data acquisition.

Camden Coalition of Healthcare Providers

How would adding this measure add value? How would the measure improve patient outcomes?

Mandating the two process measures may lead to wider adoption of social needs screening in healthcare settings. While screening itself does not imply practices will have the resources to respond effectively to the social needs identified, it at least establishes a foundation for building processes within practices and the community to address health-related social needs. Collecting structured data on social determinants could bolster efforts to understand and address equity issues in the healthcare system, improve segmentation efforts, and may be a springboard for measuring the capacity of healthcare providers to respond to social needs, and identifying where gaps between social needs and resource availability in the community exist.

Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of the measure will not necessarily outweigh the burden of data collection or reporting. This will depend on many practice-level factors, such as the ability to develop efficient screening workflows, the availability of staff who are trained and well-prepared to engage patients with complex social needs (especially around sensitive needs such as those related to interpersonal safety), the smooth integration of screening data into a practice's existing data systems, and the ease with which the data can be made available to clinicians at the point-of-care. Moreover, the interpersonal safety questions are proprietary, and from a practice's perspective, it may not be worth the cost of including those questions in their screener, especially if there are inadequate resources available to address any interpersonal safety issues a person is experiencing. We would recommend offering alternative questions related to interpersonal safety for practices who do not want to pay to use the four questions currently included in the AHC screener. Finally, with reimbursement, benefits may outweigh burden as long as practices are given flexibility in how social needs screening takes place and the reporting requirements are not cumbersome.

For what purpose are you using the measure (e.g., QI, certification/recognition, regulatory/accreditation, payment, public reporting, disease surveillance)?

The Camden Coalition is an Accountable Health Communities alignment track hub. The social needs screening data we collect are used for multiple purposes locally and regionally. For example, we share the data with health systems and other community partners for community health needs assessments and gaps analysis; we leverage the data to procure funding for various population health initiatives; we make the data available through our Health Information Exchange to inform clinical decision-making; and we share the data with researchers who study the intersection of social risk and health.

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Are there implementation challenges?

Challenges include incorporating the screening tool into practice workflows, throughput, cost, potential need for extra staffing, and storing and accessing the data. If the screener is self-administered, challenges related to staffing might be reduced, but there are other challenges that need to be considered. An efficient workflow still needs to be established - for example, determining when during a visit a patient will receive the screener and who on staff will be responsible for introducing the screener to the patient. Language and literacy barriers present challenges as well and may require additional time and support from staff. Additionally, if a practice is doing more than collecting data and is going to establish workflows to respond to social needs, there are coordination costs associated with addressing those needs. There would need to be people on staff who can have the kinds of conversations that must take place when a patient expresses a social need. This may mean hiring a social worker, for example, or taking on the cost of training existing staff members.

Carolina Complete Health

The COVID-19 pandemic and other recent events have exposed long-standing racial and economic injustices embedded in many American systems, including our health care system. Fortunately, the recent attention has either generated or renewed for many a commitment to improve health equity and address the social drivers of health (SDOH) that may account for up to 80 percent of health outcomes and have a demonstrably disproportionate impact on communities of color. Those drivers include stable, affordable housing; access to healthy food; availability of reliable income; and interpersonal safety, among others.

Because of the well-documented impact of these factors on health outcomes and costs, plus the disparate impact on people of color, we need standardized SDOH measures in Centers for Medicare and Medicaid Services (CMS) programs. Including such measures will assist CMS in realizing its pledge to collect more robust DOH data, move the needle on health equity, and address its stated measurement gap to “develop and implement measures that reflect social and economic determinants.”

Physicians and other healthcare providers have called on CMS to create standard patient-level SDOH measures – going beyond just socioeconomic status and duals status – recognizing these factors can drive physician burnout and impact providers caring for affected patients via increased financial risk through lower MIPS scores. The recent actions of the MAP groups to codify specific measures that will help to both identify and drive needed support for improvements in this vital area are appreciated. I continue to pledge my support for the MUC 134 and 136 measures before you.

The work of several CMS Innovation Center models like Accountable Health Communities, Comprehensive Primary Care Plus and others has demonstrated that screening for and acting upon these drivers of health is impactful for millions of Medicare and Medicaid beneficiaries, both in inpatient and outpatient settings. However, because this work has been done without the availability of standard SDOH measures or screening tools, CMS cannot systematically compare or use that wealth of data in a reliable fashion. The promise shown by these innovative efforts should not be minimized given the immense opportunity we have to improve overall outcomes and have meaningful impact on disparities amongst us. It should be encouraging to all that these proposed measures have been effectively implemented in AHC over 5 years now and across >1M CMS beneficiaries in 600 clinical sites and multiple practice settings across the country. It also should be reassuring that the AHC screening tool

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has been objectively shown to be reliable with concurrent and predictive validity.

The ideal convention would be use of the Social Driver of Health Screen Rate measure and the SDOH Screen Positive Rate measure in tandem. Given the disproportionate impact of SDOH on people of color, these measures account for actual screening that occurs but also recognizes providers for reporting the screen positive rate for their patients. Given the variability in the prevalence of SDOH across geographies and patient populations – as well as in clinical sites' capacity to provide patient navigation – the suggested approach for introducing such measures into the federal quality frameworks is critical.

UniteUs/NowPow, a wholly owned subsidiary of UU

Overall, Unite Us supports including measures 134 and 136 in MIPS, hospital IRQ and other value-based payment programs if the proposed measure has been tested and meets NQF or CMS MERIT-based payment or other measure quality standards. We are pleased to see that the Measure Applications Partnership (MAP) Clinician and Hospital Workgroups conditionally approved both measures for MIPs and 136 for IQR. We recommend that the MAP Workgroups also approve measure 134 for IQR.

We understand that a barrier to approval of measure 134 by the Hospital Workgroup was the concern of some members that public disclosure of rates of food insecurity and other health-related social and economic needs could negatively impact a hospital's business. Importantly, thousands of hospitals already publicly reporting these kinds of data through their Community Health Needs Assessments. These assessments commonly include rates of health-related socioeconomic conditions including food insecurity, unemployment, housing instability, transportation needs and poverty. Given the ubiquity of these conditions, it is unlikely that members of the public could or would meaningfully use publicly reported data on prevalent health-related socioeconomic conditions to decide whether or not to elect care at a given hospital or medical center.

In addition, hospitals play a critical role as both anchor institutions and data engines for communities. Public sharing of data about socioeconomic needs of people living in the primary service area enables data-driven community investments by hospitals and others and offers the opportunity to evaluate the impact of community investments on outcomes of shared importance to healthcare and community leaders. Transparently sharing social needs data empowers leaders to confront hard facts, develop targeted solutions to address unmet needs, and forge partnerships between healthcare, communities, philanthropy and government to improve health and well being.

We also note the measure does not require follow-up after needs have been identified. We recommend the creation of additional measures in the future that evaluate whether services to address social needs are provided in a timely manner. Assessing needs without addressing them will not improve quality. Despite these concerns, we believe the measure is a positive first step towards considering and tracking social drivers of health. Including these measures will encourage clinicians and staff to screen and track social drivers of health.

Social Interventions Research and Evaluation Network at the University of California, San Francisco

January 13, 2022

Dear MAP Coordinating Committee,

We are writing as leaders of the Social Interventions Research and Evaluation Network (SIREN), a center

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at the University of California, San Francisco dedicated to elevating and strengthening evidence related to programs and policies that can support health care systems to meaningfully deliver social care. We welcome the opportunity to submit new comments regarding Measure Application Partnership's Measures Under Consideration 2021-134 [Screen positive rate for social drivers of health (Hospital IQR and MIPS)] and 136 [Screening for social drivers of health (Hospital IQR and MIPS)]. These new comments supplement comments we submitted in December.

We are pleased to see that MAP offered Conditional Support for Rulemaking for the Screening for social drivers of health measure (MUC21-136) for both the MIPS and IQR programs, and for the Screen positive rate for social drivers of health measure (MUC21-134) for MIPS. We agree with MAP that these measures should move forward, conditional on NQF review and endorsement. We strongly encourage MAP to also offer conditional support for the screen positive rate for the IQR program.

We understand that a barrier to support of the screen positive rate measure (MUC21-134) for IQR was the concern raised by hospitals that public disclosure of rates of food insecurity and other health-related social and economic needs could negatively impact a hospital's business.

While we understand the concern, we think it is unlikely to be valid as thousands of hospitals are already publicly reporting these kinds of data as part of their federally mandated community health needs assessments (CHNAs) and there is no evidence this practice has had any negative impacts on hospitals.

The 2010 Patient Protection and Affordable Care Act requires that most of the nation's ~2700 tax-exempt hospitals assess, publicly report on, and address the needs of the communities they serve (Young CJ et al, NEJM, 2013). These "Community Health Needs Assessments" (CHNA) are conducted every 3 years and published with an implementation strategy to address identified needs. The majority of these reports are published online, so are already readily available to the public. In addition to disease-specific needs, these assessments commonly include rates of health-related socioeconomic conditions, including food insecurity, unemployment, housing instability, transportation needs and poverty. Using our two institutions as examples, the top hit on a Google search of "UCSF" and "CHNA" is UCSF Health's 2019 CHNA report. The problems "food insecurity," "racial health inequities and poverty," and "housing security" are the top 3 listed. Similarly, a Google search of "University of Chicago CHNA" leads, in just two clicks, to the CHNA executive summary, which shows the primary service area's food insecurity rate of 50%, poverty rate of 53%, and unemployment rate of 21%. Looking at other localities yields the same result. Review of the 2019 Texas Children's CHNA also surfaces social determinants of health as a primary focus area. In fact, it is exceedingly difficult to identify a CHNA from the last reporting cycle (2019) that does not highlight food insecurity, poverty, unemployment, and related adverse conditions as critical issues facing the communities served. Despite the ubiquity of this information, we are not aware of any evidence that this kind of information, or any other information about the prevalence of health-related socioeconomic conditions, is being used by patients to make decisions about whether or not to obtain care at a given hospital or medical center.

Informing a hospital's patient, trainee, and employee base about the health-related social needs of the community can also help drive valuable community partnerships and even philanthropy. In just one example, the University of Chicago implemented its Feed1st program in 2010 to address high rates of food insecurity (identified first by the Comer Children's Hospital chaplain and later confirmed by researchers.) The program is unique from other hospital-based food assistance programs in that it is

fully self-serve, available to both patients, visitors, and staff, and all users are encouraged to both take as much as they need and to contribute back if they can. This highly transparent, no stigma, no barriers, asset-based approach to emergency food assistance has been sustained for more than a decade with the help of volunteers and donors who learned about the problem of food insecurity during their stay or work in the hospital. In one notable instance, a family member of a child hospitalized for 20 days of radiation treatment found meaning in rallying their own family and friends to supply the hospital pantry to alleviate the suffering of others during their own child's hospital stay (Makelarski et al, AJPH, 2015). Rather than deterring business, bringing attention to social needs such as food insecurity can therefore connect patients more strongly to the institution. We believe these kinds of positive outcomes are much more likely than any loss of business when hospitals share information on remediable social and economic problems affecting the health and well-being of the people and communities they serve.

Furthermore, hospitals play a critical role as both anchor institutions and data engines for communities. Public transparency about the prevalence of health-related socioeconomic and other stigmatized conditions is essential for both public trust in and accountability to the communities these medical centers serve. Public sharing of data about the socioeconomic needs of people living in the primary service area enables data-driven community benefit investing by hospitals and linking of community investments to outcomes of shared importance to the business of healthcare and the business of the broader community.

Finally, as in our previously submitted comments, we encourage inclusion of a little more measure specification to address the following issues:

- It is our understanding that measure 136 (screening) is meant to only count beneficiaries screened for all five risks (vs. any of the five risks) and that the screening positivity measure (134) is meant to count beneficiaries with at least one of the needs (not only those who have all five). However, the way the measures are defined do not make this explicit.
- The measure definitions also do not specify whether clinicians and hospitals can use any screening tool or approach or whether there is a required set of questions or tools that should be used. Despite hoping for future standardization, we currently would recommend allowing flexibility in how different social domains are measured because since there are a variety of assessment tools already in use across the country.

In sum, we hope MAP will give its most serious consideration to these insights and shift its decision in support of their MUC 2021-134 Screen positive rate measure recommendation to conditional support. And we recommend that the measure specifications be slightly clarified to address areas of potential confusion.

We thank NQF and MAP for providing this opportunity to provide feedback about this important and growing part of high-quality patient care. Please reach out to slindau@bsd.uchicago.edu if you have any questions about these comments.

Sincerely,

Stacy Lindau, MD MAPP, University of Chicago

Laura Gottlieb, MD, MPH, University of California, San Francisco

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Caroline Fichtenberg, PhD, University of California, San Francisco

Taressa Fraze, PhD, University of California, San Francisco

Danielle Hessler Jones, PhD, University of California, San Francisco

Wholesome Wave on behalf of the National Produce Prescription Collaborative
National Produce Prescription Collaborative

January 13, 2022

To: Members of the NQF: Measure Applications Partnership

From: Members of the National Produce Prescription Collaborative (NPPC)

RE: Support for Driver of Health Screening Rate (MUC2021-136) and Driver of Health Screen Positive Rate (MUC2021-134)

As members of the National Produce Prescription Collaborative (NPPC), we are pleased to write additional comments in support of the Drivers of Health Measures currently being considered under the Measure Applications Partnership Considerations. We were thrilled that CMS accepted the "Drivers of Health Screening Rate" and the "Drivers of Health Screening Positive" measures as part of the 2021 CMS MUC list.

We greatly appreciated the MAP Workgroup's strong support for the SDOH measures for MIPS. We ask that as the map process enters its final Coordinating Committee review on January 19, that the Coordinating Committee additional recommend both SDOH measures (screening and screen positive rate) for the HIQRP. Recognizing the nexus between hunger, nutrition insecurity and the structural inequities at the heart of these issues, Members of NPPC support screening for drivers of health, including food insecurity and believe the adoption of these measures would add tremendous value and represent a crucial milestone on the path towards health equity.

We appreciate that there is a current opportunity to enact the first-ever social DoH measures in the history of health reform. CMS recently included the DoH measures focused on screening patients for food insecurity, housing instability, transportation, utility needs, and interpersonal safety in its "measures under consideration" list. These measures (stratified by race/ethnicity) are well-tested in over 600 clinical sites across the country through the CMS Innovation Center's Accountable Health Communities model. Adoption of these measures will go a long way to identify gaps in patient care and health outcomes that extend beyond the four walls of a health clinic and, with strengthened community-clinical connections, curb the growing national cost burden of diet-related disease through our federal health programs.

Hospitals' reporting the screen positive rate would be important to patients by (1) providing transparency; (2) targeting community investments based on data they provided; (3) signifying hospitals' familiarity/expertise regarding these issues; and (4) enabling quality improvement activities, including addressing disparities. As you know, diseases linked to poor diet are the most frequent causes of death in the United States, and diet is the leading risk factor for premature death worldwide. Reducing even a fraction of this burden by improving people's diets would save countless lives. The COVID-19 pandemic has brought renewed focus to gaps in access and infrastructure that limit the ability of our federal

health care and food assistance programs to address the issues of nutrition, food insecurity, and health. COVID-19 has also exposed the long-standing burden of diet-related chronic disease. Unfortunately, these diet- related diseases disproportionately affect low-income households, racial and ethnic minorities, and elderly people, highlighting the wounds of systemic racism and disparities in the US economy, food systems and healthcare systems.

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National Produce Prescription Collaborative

While a growing number of CMS Innovation Center models are incorporating DoH screening and navigation on social needs, they use varied tools and approaches. As a result, CMS cannot systematically compare or use the data. The same is true for race and ethnicity data, which currently are measured or reported inconsistently across CMS programs. NPPC members and partners are developing and deploying programs and platforms and are seeking robust research capacity to support community-rooted health organizations in their efforts to address the lack of affordability and access to healthy food across the country.

Applying these measures to both the merit-based Incentive Payment System and the Hospital Inpatient Quality Reporting Program — would go a long way to improve patient outcomes. At the same time, it would provide a crucial foundation for comparable measures to be adopted by the Medicaid Adult and Child Core Measure Set while providing critical guidance for states in their efforts to standardize DoH data. Furthermore, by reporting the screen positive rate for food insecurity, hospitals would be well-positioned to take action, including (for example) implementing produce prescription programs, which are demonstrating their value by improving the health outcomes of people struggling with diet-related diseases such as diabetes, high blood pressure, and kidney disease by increasing dietary quality and treating the stresses of food insecurity.

Evidence of Produce Prescription Programs

The Produce Prescription intervention began just over a decade ago. Today, more than 100 organizations administer them across the country.

A growing body of evidence, including 30 studies in peer-reviewed scientific and economic journals in the past 5 years, suggests that Produce Prescriptions improve intake of fruits and vegetables, improve overall dietary quality, reduce the gap between actual daily consumption and the national recommendations, lower weight, lower blood pressure, and lower Hemoglobin A1C — the biometric indicator used in diagnosing for diabetes and prediabetes.

Due to early promising results, Medicare Advantage plans have implemented Produce Prescriptions alongside other food and produce through the allotment for Special Supplemental Benefits for the Chronically Ill (SSBCI). From year one (2020) to year two (2021) plans offering these food and produce benefits have grown from 101 to 347, a 244% Medicaid managed care plans in several states have also implemented Produce Prescription programs through various flexibilities allowed using 1115 waivers.

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Screen Positive Rate for Social Drivers of Health

Having DOH measures available to screen for food insecurity will help these government-sponsored health plan practitioners deliver on the growing promise of food as medicine. For example: In North Carolina, Reinvestment Partners and Blue Cross NC are launching an RCT that compares Produce Prescriptions and healthy food boxes for 6- or 12-month enrollment periods. Reinvestment Partners is also participating in an evaluation as part of Healthy Opportunity Pilots (under North Carolina's 1115 waiver). NC programs beneficiaries must have at least one qualifying physical or behavioral health condition and have one qualifying social risk factor. Of interest, partnering with insurers and providers, including 2 major health systems (Duke Health and Atrium Health, the state's largest provider network); 9 Federally Qualified Health Centers; 30+ county level WIC, DSS Offices, and health departments; and 100+ staff at a statewide care management agency (Community Care of North Carolina). The breadth of this program expansion is a demonstration that effective collaboration is possible in diverse healthcare settings and early research is showing promising impacts on food insecurity.

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Likewise, Wholesome Wave's Fruit and Vegetable Prescription Program® (FVRx®), which ran in 12 states across the country, reached thousands of individuals who struggle with diet-related illness. FVRx reached 2300+ recipients in a 2016 Los Angeles pilot and was expanded to communities and health centers in Houston and Miami, Hartford and Sacramento and has helped more than 5,000 people. In the pilot, 93% of participants met produce-consumption guidelines by the program's conclusion, with a 128% increase in the number of cups of fruits and vegetables consumed. Among people at high risk of developing diabetes, those taking metformin lowered their risk of getting diabetes by 31% compared with those taking a placebo, while those who modified their diet and exercised regularly lowered their risk by 58% compared with those who didn't change their behaviors, a near doubling in risk reduction.

Additionally, the Washington State Department of Health has partnered with twelve health care systems and public health agencies and a large grocery chain to redeem over a million dollars in produce prescriptions from 2016 through 2020.

Having a Drivers of Health Screening Rate (MUC2021-136) that screens for food insecurity will provide vital insights to addressing nutrition insecurity for qualified patients enrolled in Medicare, and help determine who will benefit from the intervention. This will be a vital step to adoption of Produce Prescription interventions within the healthcare system. The members of the National Produce Prescription Collaborative recommend including these measures among those the MAC moves forward for consideration.

About NPPC

The National Produce Prescription Collaborative (NPPC) is a group of produce prescription practitioners, researchers, and advocates, who gathered in 2019 to catalyze the vital role of food and nutrition in improving health and wellness by collectively leveraging the unique opportunities for Produce Prescriptions to achieve wellness by embedding and institutionalizing Produce Prescriptions within

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healthcare practice. Our respective organizations are actively working to bring new and innovative Produce Prescription models to communities across the country.

NPPC defines a Produce Prescription program as a medical treatment or preventative service for patients who are eligible due to a diet-related health risk or condition, food insecurity or other documented challenges in access to nutritious foods, and who are referred by a healthcare provider or health insurance plan. These prescriptions are fulfilled through food retail and enable patients to access healthy produce with no added fats, sugars, or salt, at low or no cost to the patient. When appropriately dosed, Produce Prescription programs are designed to improve healthcare outcomes, optimize medical spending, and increase patient engagement and satisfaction.

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AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. Conceptually, we support the idea of the Screen Positive Rate measure as we would like to see equity measures that go beyond screening rates and promote action to address social risk. While we agree the information on who screens positive would be useful to physicians and hospitals so they can provide assistance, we believe this measure must be implemented carefully to avoid unfairly penalizing providers serving vulnerable populations.

While we support the confidential provision of this information to providers for the purposes of performance improvement, we would like more information on how this measure would be benchmarked for public reporting or payment before recommending its use for these purposes. We agree with the need to ensure patients are referred to needed services but do not believe this measure should be tied to payment or publicly reported until there is more information about how it performs.

We also recommend that CMS work with the measure steward to refine this measure to include specific screening tools or provide implementation guidance on which screening tools should be used to promote consistency in screening for social determinants across the healthcare sector. Additionally, we recommend that CMS and the measure steward work to ensure alignment with accepted data standards for SDOH. We would recommend that CMS and the measure steward look to the work of the Gravity Project to identify data standards. Ensuring consistency in the screening tools used and utilizing the work of the Gravity Project would align with work health care providers, electronic medical records companies, RHIOs, health insurance providers and government agencies are doing to address SDOH.

OCHIN, Inc.

This measure is essential to identify and remedy persistent structural inequality that adversely impacts patient outcomes—and this is equally true whether patients are receiving care in ambulatory or in-patient settings. This measure creates incentives for the clinical team to identify structural barriers to improved health care and associated social and other services that could facilitate improved patient health status, including improved access to care. Clinicians and providers cannot address social determinants of health if this information is not collected and acted upon. Our nation's health care delivery models must embed incentives—such as quality measures--to improve care for patients facing the greatest barriers to health care and other structural inequities. The need does not change based on

site of care since the patient faces the same social risks.

Recommendations: OCHIN urges the Committee to rescind its current recommendation and also provide conditional support for rulemaking with regard to MUC21-134 (IQR) as this measure is needed to advance the same fundamental goal: health equity. Patients are at their most vulnerable when they are admitted to the hospital. Understanding their SDOH is critical to assess risks in follow-up, recuperation, and rehabilitation. And the only way to understand the services that may be needed is to assure that there is reporting of the findings of SDOH assessments.

OCHIN is a nonprofit health information technology innovation and research network that serves over 1,000 community health care sites with 21,000 providers in 47 states serving nearly 6 million patients. The OCHIN network provides a continuous learning health system collaborative and offers technology solutions, informatics, evidence-based research, and policy insights. For two decades, OCHIN has advanced equitable health care solutions by leveraging the strength of our network's unique data set and the practical experience of our members to drive technology innovation at scale for patients and providers in underserved communities. To that end, OCHIN network members have documented over 1 million individual patient screenings for SDOH. The screening, evaluation, and use of this information is complex, challenging, and hinges on preserving patient trust. This is a resource intensive process that requires adequate time, workflow design, patient engagement, and staff and clinician training. The benefits of the measures outweigh the burden of data collection and reporting where flexibility is provided to optimize workflow and staffing needed to collect the information with the goal of reducing cognitive burden and enhancing team-based approaches to care while preserving and safeguarding patient-clinician relationship and privacy.

These measures are needed for quality improvement activities, payment, research, and public health activities including disease surveillance and mitigation measures in order to address health care inequity. In light of the USCDI adoption of SDOH domains and elements, the suitability of this information can inform numerous clinical, public health, and policy needs to improve care overall equitably. Adding information on social complexity to payment discussions could provide valuable insight for value-based payment and care arrangements and risk-bearing contracts.

We offered in our initial round of comments, as we do here, conditional support for these measures. OCHIN recommends that the measures for interpersonal safety domain be removed. Current approaches to addressing relationship safety and intimate partner violence (IPV) are moving away from screening towards a universal education and harm reduction approach. Futures Without Violence (FWV), the CMS partner for IPV prevention and education nationally, notes that while that 1 in 4 women experiences IPV in her lifetime, disclosure rates in practice are usually less than 10% (around 5-6% among OCHIN network members' patients), indicating significant underreporting and calling the utility of collecting this data into question. Instead, FWV provides and promotes a framework called CUES that addresses confidentiality (including its limits in required reporting settings), universal education about healthy relationships, and support for any disclosure that includes warm handoff to appropriate resources. Given this disparate approach, OCHIN recommends not including IPV in the current measures. OCHIN would, however, support a separate measure for IPV focused on the provision of universal patient education.

OCHIN has previously advocated for inclusion of SDOH in screening measures and data standards to

begin with the domains of housing, food insecurity, and transportation as “core” domains appropriate for screening in most every community and patient panel. The addition of utility assistance aligns with research from the SIREN group at University of California (San Francisco) that finds these four domains (housing, food insecurity, transportation, and utility assistance) are the most impactful for screening and action in healthcare settings. Consequently, these are the appropriate domains to include in such measures at this time. In the future, other domains could either be optional based on appropriate community or clinic considerations or added as more evidence about the relationship between SDOH and health becomes available.

University of Chicago, Section of General Internal Medicine

1. How would adding this measure add value? How would the measure improve patient outcomes?

As the National Program Office team at the University of Chicago we work with eight grantee organizations from the Merck Foundation funded Bridging the Gap: Reducing Disparities in Diabetes Care initiative. These organizations are transforming primary care through integrated medical and social care to improve diabetes care and outcomes. We have a national lens on integrated medical and social care activities to support chronic disease care. The initiative transforms primary care through the implementation of integrated strategies to address SDOH, with evolving payment models to support these transformations.

The measures (MUC2021-134 (Screen Positive Rate for Social Drivers of Health) and MUC2021- 134 (Screening for Social Drivers of Health)) add value by providing an opportunity to change how and what we measure in health care. The opportunity to measure drivers of health (DoH) allows health care teams to have data to identify and address unmet needs and policymakers and payers to account for DoH in health care delivery and financing models. For example, grantees in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have utilized DoH screening at two levels: to understand individual patient needs and to assess the needs across their population. Health care teams have utilized screening to assist with resource allocation and to tailor care for individual patients. At the population level, grantees have harnessed this high-level to better inform the support services needed and to establish critical cross-sector partnerships.

These measures have the potential to improve patient outcomes by establishing approved, standardized DoH measures in Centers for Medicare and Medicaid Services’ (CMS) programs. Standardized collection of DoH measures would allow CMS to systematically compare or use the data. DoH measures can provide insight into the social factors that facilitate or constrain optimal health, particularly for vulnerable populations (e.g., older adults, communities of color). Assessing these factors in a standardized way is an important first step towards improving equitable health outcomes.

2. Do the benefits of the measure outweigh the burden of data collection or reporting?

The benefits of these DoH measures outweigh the burden of data collection or reporting. These measures are well tested, including through the Accountable Health Communities model, which screened nearly a million beneficiaries for SDOH in over 600 clinical practices.

3. For what purpose are you using the measure (e.g., QI, certification/recognition,regulatory/accreditation, payment, public reporting, disease surveillance)?

The National Program Office at the University of Chicago has utilized positive DoH screening results to

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better understand the scope of social needs amongst the study population within our initiative, especially among medically high-risk populations. Grantees within the initiative utilize different screening tools and the standardization of DoH screening data has proved to be an area of difficulty in the evaluation process.

4. Are there implementation challenges?

To address implementation challenges it is imperative to plan for documentation of these measures during data collection and options for data extraction. Technical assistance may be needed to support best practices for data collection workflows and data extraction. In addition, providers in the Bridging the Gap: Reducing Disparities in Diabetes Care initiative have highlighted that screening for DoH should not be conducted without an appropriate pathway to address the needs screened for. As part of the implementation of screening for DoH, CMS and its partners should consider developing technical assistance to ensure best practices for DoH referrals.

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MUC2021-106 Hospital Commitment to Health Equity

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting Program

Workgroup
Measure Applications Partnership Hospital Advisory Group

Measure Description
Among Medicare beneficiaries, racial and ethnic minority individuals, individuals with limited English proficiency or disabilities often receive lower quality of care and higher rates of readmission and complications than beneficiaries without these characteristics. Strong and consistent hospital leadership can be instrumental in setting specific, measurable, and attainable goals to advance equity priorities and improve care for all beneficiaries. This includes promoting an organizational culture of equity through equity-focused leadership, commitment to robust demographic data collection, and active review of disparities in key quality outcomes, which are assessed in this measure.

Numerator
This structural measure assesses hospital commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minorities, people with disabilities, sexual and gender minorities, individuals with limited English proficiency, and rural populations. The measure will include five attestation-based questions, each representing a separate domain of commitment. A hospital will receive a point for each domain where they attest to the corresponding statement (for a total of 5 points). For questions with multiple elements, attestation of all elements is required in order to qualify for the measure numerator.

Domain 1: Equity is a Strategic Priority

Question 1. Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing healthcare equity and that it includes all of the following elements. Select all that apply (note: attestation of all elements is required in order to qualify for the measure numerator):

a. Our hospital strategic plan identifies priority populations who currently experience health disparities.
b. Our hospital strategic plan identifies healthcare equity goals and discrete action steps to achieving these goals.
c. Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals.
d. Our hospital strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.

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Domain 2: Data Collection

Question 2. Collecting valid and reliable demographic and social determinant of health data on patients served in a hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities. Select all that apply (note: attestation of all elements is required in order to qualify for the measure numerator):

a. Our hospital collects demographic information, including self-reported race and ethnicity, and social determinant of health information on the majority of our patients.
b. Our hospital has training for staff in culturally sensitive collection of demographic and social determinant of health information.
c. Our hospital inputs demographic and social determinant of health information collected from patients into structured, interoperable data elements using a certified EHR technology.

Domain 3: Data Analysis

Question 3. Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your hospital engages in the following activities. Select all that apply (note: attestation of all elements is required in order to qualify for the measure numerator):

a. Our hospital stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.

Domain 4: Quality Improvement

Question 4. Health disparities are evidence that high quality care has not been delivered equally to all patients. Engagement in quality improvement activities can improve quality of care for all patients. Select all that apply (note: attestation of all elements is required in order to qualify for the measure numerator):

a. Our hospital participates in local, regional, or national quality improvement activities focused on reducing health disparities.

Domain 5: Leadership Engagement

Question 5. Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your hospital engages in the following activities. Select all that apply (note: attestation of all elements is required in order to qualify for the measure numerator):

a. Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews our strategic plan for achieving health equity.
b. Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews key performance indicators stratified by demographic and social factors.

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Numerator Exceptions
There are no Numerator Exceptions

Denominator
The denominator for each hospital is 5 which represents the total number of questions.

The measure is calculated as the number of complete attestations / total number of questions. There is no partial credit for any question. Attestation of all elements is required in order to qualify for the measure numerator

For example, if a hospital affirmatively attests to all elements for only 2 questions; the final score is 40% (2 complete attestations / 5 total questions)

Denominator Exclusions
There are no denominator exclusions

Denominator Exceptions
There are no denominator exceptions.

State of development
Specification

State of Development Details
Stakeholder Engagement Plan: We will solicit information on the usability, acceptability, and face validity of the proposed measure to inform the creation of the final specification. We issued a Requestion for Information in FY2022 IPPS, soliciting stakeholder feedback on the conceptual principles of the measure. We will conduct formal stakeholder engagement including senior hospital leaders to provide subject matter expertise around technical priorities for measurement. Input from stakeholders will inform finalization of technical specifications.

Field Testing Plan: Although we have not finalized the field-testing plans, we intend to conduct a representative sample of U.S. acute care hospital of various size, characteristics, and composition to assess the reliability and validity of the measure results. This includes assessing test-retest reliability and examine the concordance with other known measures of hospital performance, including the CMS disparity methods, which assess equity in hospital outcome measures.

What is the target population of the measure?
Hospitals serving Medicare Fee for Service beneficiaries

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Other: To be determined/All

Measure Type
Structure

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

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What data sources are used for the measure?
Other: Provider data entry (attestation-based statements)

If applicable, specify the data source
N/A

If EHR 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?
Other: Testing is to be determined

What one healthcare domain applies to this measure?
Equity

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
No

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If eCQM, enter Measure Authoring Tool (MAT) number
N/A

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
N/A

Evidence that the measure can be operationalized
The data source for the structural measure is self-attestation by hospitals participating in the Hospital Inpatient Quality Reporting Program.
CMS has previously collected attestation-based measures, such as the proposed measure under consideration. Attestation may be provided to CMS using existing electronic data submission portals with minimal administrative burdens.

How is the measure expected to be reported to the program?
Web interface; Other: Expected to use data fields in electronic sources, in EHR or through a web interface

Feasibility of Data Elements
No data elements are in defined fields in electronic sources

Evidence of Performance Gap
N/A

Unintended Consequences
For hospitals that do not meet the five areas emphasized in this measure, this could create burden to address the measurement area and move resources from other areas of focus. Because this is a structural measure, there is no direct assessment of improvement in quality on the basis of these actions. However, the intent of measurement is to support hospitals making needed investments in leadership, data and culture to advance equity.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Not yet developed

Estimate of Annual Improvement in Measure Score
Not yet developed

Type of Evidence to Support the Measure
Systematic Review

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
Not Applicable

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Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Unable to determine

Cost Avoided Annually by Medicare/Provider
Unable to determine

Source of Estimate
Unable to determine

Year of Cost Literature Cited
Unable to determine

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
No

If yes, choose all methods that obtained clinician and/or provider input
N/A

Total Number of Clinicians/Providers Consulted
N/A

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Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
N/A

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
Not yet tested

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Not yet tested

Reliability Testing Sample Size
N/A

Reliability Testing Statistical Result
Not yet tested

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Not yet tested

Validity Testing: Type of Validity Testing Analysis
Not yet tested

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Validity Testing Sample Size
N/A

Validity Testing Statistical Result
Not yet tested

Validity Testing Interpretation of Results
Not yet tested

Measure performance – Type of Score
Other: 5-point score

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
N/A

Benchmark, if applicable
N/A

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Section 2: Preliminary Analysis – MUC2021-106 Hospital Commitment to Health Equity

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: Although health equity is not specifically cited as a high-priority area for IQR, this Measure Under Consideration advances the Equity of Care Meaningful Measure Area and would be the first Equity of Care measure in the set.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: No

Justification and Notes: The existence of healthcare disparities, and their connection to healthcare providers, is well-documented in the literature: most comprehensively by the then-IOM in *Unequal Treatment* (2003). More recently, a variety of systematic reviews documenting same have been published, including trauma outcome disparities based on race and socioeconomic status by Haider et al, or in colorectal cancer by Carethers and Doubeni, or in stroke care by Skolarus et al. The measure assesses a selection of hospital actions to address these and other disparities like them that is consistent with literature and advocacy on the subject. For example, in 2012 the American Hospital Association published a call to action putting data collection at the center of the effort to reduce healthcare disparities. A 2017 strategic plan by the AMA incorporates many of the same points, as does a similar plan by the IHI.

Nevertheless, there is little empirical evidence directly connecting the elements of the measure to improved clinical outcomes (e.g., "there is a dearth of evidence on effective structural interventions focused explicitly on health disparity outcomes" from Brown et al, 2019). Instead, there are many one-off examples of successful interventions by hospitals (e.g., breast cancer mortality disparities in Ansell et al, HIV outcomes disparities in Sherer et al).

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: Although healthcare disparities are well-established in the literature, a facility-level performance gap on the specific elements listed by this measure is not established in the literature. Face validity of the measure constructs and field testing of the measure have not been conducted, so no information about a performance gap on the measure itself is available.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: There are no comparable measures currently in the Hospital IQR Program measure set.

Can the measure be feasibly reported?

Yes/No: Yes

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Justification and Notes: The MUC can be electronically reported through a web portal, with what the developer characterized as "minimal administrative burden". However, it is important to note that in addition to the process for reporting the measure itself, the hospital would need to individually assess 11 elements of its own structure, which would entail cross-departmental and leadership fact-finding, and a close read of exact specifications to ascertain whether the hospital's initiatives are consistent with the framework set out by CMS in this measure. This data collection process may be time consuming, depending on the administrative size of the hospital.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: No

Justification and Notes: The measure is specified for hospitals, an appropriate fit for the IQR program. The actions assessed by the measure, such as the development of strategic plans, data collection, and program evaluation are all within the control of the hospital. Testing has not yet been conducted.

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?
Yes/No: No

Justification and Notes: The measure is not in use. MAP also noted that this measure may be difficult to interpret when publicly reported,

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- The elements of the measure seem appropriate for rural settings
- Not seeing any evidence in the literature for the elements of this measure to clinical outcomes
- Not clear if the performance on the elements would link to payments, need clarification of this within the program
- There was some question on whether patients are engaged in their primary language, and the developer provided a response that hospitals can leverage internal resources to engage their patient populations with differing languages
- Overall, the Advisory Group agreed that this measure has importance

Data collection issues:

- Don't see any burden for reporting, it would be electronic.
- Any burden may be the assessment of the questions, but not for reporting

Calculation issues:

- None

Unintended consequences:

- Hospitals that don't meet the elements, it could create a burden to address the measurement area, which may require moving resources from other priority areas

Votes: Range is 1 – 5, where higher is more relevant to rural.

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Average: 3.9
1 – 0 votes
2 – 1 votes
3 – 3 votes
4 – 7 votes
5 – 4 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- There are certain things not present in the measure, such as community engagement and transparency (i.e., it didn't specify that the data collection and reporting are shared with the public)

Data collection issues:

- None

Calculation issues:

- Issues with standardization on the 'commitment' for measurement
- Will there be an analysis of this measure in correlating it with health disparities and quality of care? CMS responded that over time there will be correlations to outcomes. The developer mentioned that this measure is the first step in signaling hospitals are improving health disparities

Unintended consequences:

- There may be a danger that this sets too low of a bar with this measure. Concern that this measure is not really measuring what is going on, as hospitals may signal that they are committed to improving health equity, but the challenge is trying to see what is really going on. The Advisory Group also noted that this measure may be difficult to interpret when publicly reported,

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.7
1 – 1 votes
2 – 2 votes
3 – 3 votes
4 – 9 votes
5 – 4 votes

Recommendation

Preliminary Analysis Recommendation:
Do Not Support for Rulemaking

Summary: What is the potential value to the program measure set?
This measure assesses whether the hospital has developed a plan to address health equity

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issues, has collected and analyzed the data needed to act on that plan, and has evaluated their progress towards attaining their objectives.

Summary: What is the potential impact of this measure on quality of care for patients?
Reducing healthcare disparities would represent a substantial benefit to overall quality of care. However, the literature currently does not closely link this measure to clinical outcomes; likewise, a performance gap at the individual hospital level on these specific structural elements has not been established in the literature.

In summary, there is insufficient information to evaluate the potential impact of this measure on quality of care.

Section 3: Public Comments

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 Measures Application 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 assessment of surgical care value 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 celebrates the direction of the Hospital Commitment to Health Equity structural measure and commends CMS for proposing this measure in IQR. This measure puts together quality as a true program instead of sporadic measures, and we applaud that. CMS explains that this measure intends to assess promoting an organizational culture of equity through equity-focused leadership, commitment to robust demographic data collection, and active review of disparities in key quality outcomes. ACS supports the direction of this measure and believes that these structural objectives are key to driving quality improvement. The ACS has decades of experience developing ACS quality programs which are based on the ACS Quality Model framework, including ACS Trauma Center Verification, Bariatric Surgery Accreditation, and the Commission on Cancer Accreditation, to name a few. These programs have a history of aligning facility and providers for seamless, continuous reliable standardized care. ACS programs includes attributes such as demonstrable commitment to surgical quality from the C-suite; appointment of a surgical quality officer and surgical quality committee; establishment of a hospital safety culture; a formal case review process; standard surgeon onboarding, credentialing, and privileging policies; data systems organized to find problems (such as complications and inefficiencies) and fix them; and so on. In our experience running ACS Quality Programs, this framework has demonstrated the ability to drive improvements in care and provides the appropriate structures and resources, while promoting a culture of quality. The Hospital Commitment to Health Equity structural measure supports many of these principles. In surgery, the ACS asserts that a quality program includes structural measures combined with process and key outcome measures for a clinical domain. We support this framework regardless of whether it is being used as part of a payment incentive programs and are supportive of similar types of structural measures in surgical care. Comprehensive quality programs have provided so much more than just holding clinicians accountable

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to specific quality measures. As a patient, wouldn't you want to go to a hospital that has gone through a quality verification program for your illness, such as cancer care? Patients want to know that they are going to a hospital that has come together to align structure, process, and outcome measures in a clinical domain with external review to achieve patient centered high quality care. Additionally, the ACS commends CMS for the resources it has invested in identifying ways to promote health equity and agrees that identifying means to improve the health care of certain populations who have been historically underserved should be a top priority of the Agency and the entire US health care system. Instead of risk adjusting away patient differences, we support measures that shine the light on health inequities at the local level, which we believe this measure begins to do. However, once the inequities are identified, how will hospitals identify the root cause? The next iteration of structural measures will need to consider strategies to develop solutions to the problem.

Phreesia

Phreesia applauds the robust attestation outlined for hospitals in this measure, and furthermore that under part 2 of the numerator there is language around ensuring a majority of patients are screened, staff is trained to collect these data, and interoperable EHR formats are used. This is a crucial step in achieving equity. However, these initiatives will be incomplete with respect to achieving equitable health outcomes without patient self-reporting on demographic and social needs data. For demographics, self-identification is broadly recognized as the best means for ensuring patients' race, ethnicity and language data is accurate. Additionally, many health systems are now initiating or scaling SDOH screening, where patient self-reporting is crucial. Most are accomplishing this through verbal collection programs, though our experience shows that digital screening tools are by far more effective in accurately capturing patients' demographic and social needs information.

In general, failing to effectively capture patient demographic and social needs information has the potential to erode trust in the healthcare system among minority groups whose trust is already significantly low. However, when given the opportunity to input their own demographic data, we have found that patients are able to accurately provide key information and can play a key role in improving their own care by closing gaps in data. Phreesia encourages CMS to encourage hospitals to administer patient self-reporting of demographic and social need data as part of their commitment to health equity.

Premier, Inc.

Premier conceptually supports adoption of new measures focused on health equity. However, we are concerned that this measure will add little value to ongoing efforts to improve health equity. The goals of this measure could be better achieved through other initiatives that CMS and HHS are pursuing to promote health equity. If CMS pursues a structural measure it should be specific to advancing specific efforts. For example, a structural measure on collection of SDOH will better support CMS efforts to understand how to incorporate SDOH information into quality and payment.

The Coalition to Transform Advanced Care

We support this measure as we feel it will add value by requiring the collection and analysis of this important information. That could ultimately reduce inequity by improving patient outcomes in communities who suffer from disparities. Disparities cannot be addressed if a hospital is unaware that they exist, and we agree that data collection is a first step to begin remediating inequity.

This measure could be used for QI, certification, accreditation, payment, and public reporting purposes.

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Our implementation recommendation is that the local community be involved in this effort so that any data collected, and the method by which it is collected, be of value to the community as well as the hospital and be endorsed by the community as well.

American Medical Association

While the American Medical Association (AMA) supports the integration of health equity strategies and initiatives throughout a hospital's leadership and the entity's overall structure and practices, we do not believe that the development of a structural measure, particularly one that primarily looks for the presence of equity-focused documents, in the absence of any demonstrated linkage to improvement in patient outcomes should be pursued. This approach could increase administrative burden to report a measure that does not drive the improvements we all desire and would be one that will top out quickly. We encourage CMS to shift focus from developing this type of measure and target those measures, initiatives, and activities that prioritize the collection and reporting of additional relevant disparities data and promote interventions that address them. We strongly believe that initiatives or programs that are considered to address inequities are best addressed through small pilots and tests and rolled out through a scaled approach and not within national accountability programs. As a part of the AMA's efforts to reduce health care inequities, we are currently in the process of developing a collaborative with health systems across the country that will leverage data- driven approaches to confront and overcome health disparities. The program design will drive equity in health care by leveraging the foundational concepts of quality and safety improvement practices and making equity improvement an integral part of health care practice. The key objectives cross domains from patient care to operations to quality initiatives to culture and education. The framework to guide the AMA's work is based on five key drivers:

- Driver 1: Integrate Equity into all Quality, Safety and Risk Analyses
- Driver 2: Use Equity-Informed High-Reliability Education
- Driver 3: Use Data to Support Equity Improvement
- Driver 4: Leadership Awareness and Engagement
- Driver 5: Organizational Accountability to Stakeholders As we continue to collaborate with health systems to test this framework and determine any unintended consequences, the AMA continues to support efforts to pilot test innovative strategies to improve health equity and reduce disparities. Because we do not believe that a structural measure at the national level will result in effective change, we request that the highest level of MAP recommendation be "Do Not Support."

Federation of American Hospitals

The Federation of American Hospitals (FAH) and its members are fully committed to achieving equity in the provision and quality of health services and we believe that many of the priorities included in this structural measure are currently addressed by hospitals and health systems. Many already have in place language and communication access plans woven into their frameworks for ongoing provision of culturally competent care to patients with limited English proficiency and hearing or vision disabilities. These plans typically form part of the curricula for onboarding and refresher training of patient-facing staff. Hospitals also maintain certified electronic health record technology (CEHRT) capabilities as required under the Centers for Medicare and Medicaid Services (CMS) Promoting Interoperability Program for hospitals. These activities also overlap with accreditation requirements of hospitals generally or of special hospital programs (e.g., accreditation of bariatric surgery programs that mandates

culturally competent care of morbidly obese patients). Hospital associations already have underway a variety of programs addressing equity, including organizational focus and leadership. The FAH urges CMS to first catalogue what hospitals are already doing before establishing new measures or requirements to preclude burden caused by overlap and redundancy. A complete environmental scan, listening sessions, focus groups, and/or a Technical Expert Panel would be helpful. In addition, the FAH believes that CMS has the opportunity to address inequities in care through existing measurement efforts. For example, the collection of race/ethnicity, payer, and gender have always been included in the electronic clinical quality measure (eCQM) specifications as supplemental data elements. CMS could choose to make the collection and reporting of these data required. This change would allow hospitals to collect the data, use it for improvement purposes, and receive automatic credit through reporting of these data rather than require them to attest to it through a structural measure. Further specificity regarding what would specifically satisfy each of the statements is also needed to ensure that every hospital interprets and attests to them consistently. For example, what constitutes a majority of patients under question 2b and what are the minimum requirements for participation in a local, regional, or national quality improvement activity under question 4a? Because of the importance of this issue, the FAH regrets that we cannot support consideration of this measure at this time due to the need for additional specificity and lack of clear linkages that each of the statements as currently defined can improve outcomes in health equity. The FAH encourages the CMS to explore other measures that are more directly linked to quality improvement and accountability while also minimizing reporting burden for hospitals. As a result, the FAH requests that the highest level of MAP recommendation be “Do Not Support”.

Missouri Hospital Association

The Missouri Hospital Association applauds the conceptual spirit and intent of Measure Under Consideration 106: Hospital Commitment to Health Equity and its genesis, Executive Order 13985. We appreciate the thoughtful approach of the Centers for Medicare and Medicaid Services in requesting information on how best to advance health equity in a way that balances the resources that will be required to fill the many data gaps surrounding social determinants of health, more finite constructs of race and ethnicity, sexual orientation and gender identity, and health disparities with pragmatism.

MUC 106 is designed to capture self-reported cultural information on organizational core competencies and institutions aimed at promoting health equity through resources and practices explicitly dedicated to minimizing health disparities. The data generated through the attestation process will be burdensome for respondents and incredibly difficult for CMS to validate. However, the sheer existence of the instrument may independently serve as a significant catalyst for the culture change needed to induce the embrace of health equity promotion among late adopters and organizations that may not realize they have an important role in this space due to racially and ethnically homogenous case mixes. At the same time, we share the concern of many resource-constrained rural and Critical Access Hospitals that the instrument as currently designed may cause confusion for respondents without supplemental educational resources including, but not limited to, rural and urban case-studies, evidence-based best practices, applied examples of static and interactive dashboards, sample strategic planning, policy language and board resolutions.

According to the U.S. Census 2020 American Community Survey, Missouri’s population is 80.1% non-Hispanic White. Among Missouri’s population 65 and older, who are most likely to seek care in a hospital setting, and who constitute the primary bolus of Medicare beneficiaries in the state, the portion

increases to 88.6%. In addition, the majority of the state's racial and ethnic minorities reside in its major metropolitan areas. The 2020 ACS data reveal 64 of the state's 115 counties (56%) have populations aged 65 and older that are 97% or more non-Hispanic White, while only seven counties (6%) have older populations that are less than 90% non-Hispanic White. As a result, during fiscal year 2020 Missouri's 35 CAHs reported 93.5% to 99.1% of inpatient and emergency department patients, aged 65 and older, as being non-Hispanic White in all-payer administrative claims data.

Diversity, equity and inclusion often are viewed along racial and ethnic lines among individuals and institutions less versed on the principles of health equity. As a result, we are concerned that the net benefit induced by MUC 106 will be considerably diminished without complementary educational resources and training opportunities on culturally competent, trauma-informed care and data generation processes. In general, we are supportive of the conceptual design and aims of MUC 106, however, we strongly recommend a measured and incremental deployment with supplemental education and training collateral, and potentially employing a phased pilot approach depending on hospitals' maturity in this space and underlying diversity in primary service areas. This also would allow for scientific validation and standardization of the instrument. We are apprehensive a blanket deployment of the measure, as currently designed and in isolation, will result in another set of boxes to check for hospital administrators in lieu of inducing meaningful and sustainable culture change.

With thoughtful design and deployment, MUC 106 will do much to describe and advance the state of health equity promotion among the nation's hospitals and health systems. However, CMS also needs to address the existing dearth of standardized, yet meaningful and widely available patient-level data on issues related to health equity. At the same time, and in reflection of our earlier point on pragmatism, the data generation processes required to meaningfully measure health disparities within and between finite population segments will be an expensive, yet necessary process. For example, most hospitals currently collect detailed information on patient SDOH, yet evidence suggests those data rarely are matriculated into administrative claims data systems in the form of ICD-10-CM Z-codes for the wider use in health services research and policy-setting applications. [1-3] Ensuring the systematic capture of information on patient-level SDOH and other factors, in addition to the technology required to harmonize electronic medical records systems with administrative claims billing systems will require a significant government investment to offset provider costs.

Recognizing that improving data collection through policy and incentive frameworks is the first step required in advancing health equity, that act in isolation will do nothing to improve the health and well-being of socially complex and historically underserved Americans. This infinitely more complex step will require significant government investment in the form of direct provider reimbursement for the provision of social care, a model that has been tested by CMS through optional supplemental benefit packages, Medicaid waivers and other programs. Furthermore, asking patients about sensitive issues such as homelessness, sexual orientation, gender identity and food stability is a delicate process that can be prohibited by having a lack of resources to do anything meaningful with the information shared between patient and clinician. Providing health care providers with resources required to effectively intervene with patients' health-related social needs also will make the act of generating the data less frustrating for both patient and clinician alike.

General Observations: In Question 2, demographic and SDOH information should be treated independently, and part C should include information on the use of ICD-10 Z-codes for SDOH in

administrative uniform billing systems in addition to electronic health records systems.

Question 3A may be confusing to providers in racially and ethnically homogenous areas. It may be worthwhile to include examples of ubiquitous demographic categories, such as payer type.

The premise of Question 4 is subjective depending on the type of measure being evaluated. “Health disparities are evidence that high quality care has not been delivered equally to all patients” is accurately articulated for process measures. Health outcome measures, on the other hand, are heavily influenced by upstream social and community contextual factors that may, or may not be influenceable by high quality care. Additionally, “select all that apply” is not needed.

References:

1) Truong HP, Luke AA, Hammond G, Wadhera RK, Reidhead M, Joynt Maddox KE. (2020) Utilization of Social Determinants of Health ICD-10 Z-Codes Among Hospitalized Patients in the United States, 2016–2017, Medical Care. September 11, 2020. Available at https://journals.lww.com/lww-medicalcare/Abstract/9000/Utilization_of_Social_Determinants_of_Health.98256.aspx

2) Reidhead, M., Moyer, L. & Greimann, A. (2020, January). Z Codes for Social Determinants of Health: Which Hospitals are Most Likely to Use Them and for Which Patients? HIDI HealthStats. Missouri Hospital Association. Hospital Industry Data Institute. Available at http://bit.ly/HIDIHealthStats0120 3) Reidhead, M. (2018, September). Decoding Social Determinants of Health. Missouri Hospital Association. Available at: http://bit.ly/PolicyBriefSDOH

Cerner

With changes in regulatory requirements and a shift towards a value-based paradigm, it is now more important than ever to have complete data. As data becomes more complex, we have the ability to extract multifaceted insights and provide actionable analytics to organizations striving to satisfy the triple aim at the core of healthcare reform - promoting better health, providing better care, and reducing cost.

To excel in population health management, you need to understand how patient characteristics and contextual factors, external to the care delivery process, impact your patients. We help you to better understand how these characteristics affect segments of your patient population, optimize care delivery, understand variation in outcomes related to SBDH burden, excel in value-based care and achieve health equity.

America's Essential Hospitals

America’s Essential Hospitals supports building a culture of equity and setting specific, measurable, and relevant goals to assess progress toward achieving equity priorities. While the work to eliminate disparities is not new to essential hospitals, this type of structural measure is novel and requires a thoughtful approach, including input from hospital leaders and the broader stakeholder community and NQF endorsement, before its use in CMS programs.

Current specifications include several domains with subcomponents under each domain. As noted in

NQF analyses, this measure would require hospitals to individually assess 11 elements, potentially increasing administrative and reporting burden. It is critical that a measure of hospital commitment to equity is meaningful and does not divert scarce resources away from hospitals striving to sustain access to comprehensive care while tackling social determinants of health. Further, community health needs and hospital structures vary, which might lead to differences in reporting and variability across hospitals.

Conceptually, we support the elements of this measure and our member hospitals are dedicated to advancing health equity through each of the domains in the measure. However, more work is needed to ensure meaningful application of the measure. For example, given the measure's reporting as a percentage, it is unclear how distinctions would be drawn between hospitals (e.g., what does it mean to be 60 percent committed to health equity as an organization?). Further, there is a lack of evidence demonstrating the link between elements of this measure and clinical outcomes, which is critical when evaluating the appropriateness of a measure to improve quality of care.

America's Essential Hospitals looks forward to working with our members, given their longstanding commitment to providing high-quality care to all, as well as NQF, CMS, and other stakeholders, to advance equity measurement.

American Heart Association

AHA is strongly committed to promoting health equity and supports the intent of this measure. However, the collection of robust demographic data and active review of disparities in key quality outcomes needs to be supported in order to be accurately measured, likely from sources outside the hospitals that are committed to these issues. In addition, further details on how this measure will be able to differentiate between hospitals that deliver higher and lower quality care and how the data will be used to improve health equity in these hospitals, rather than using this data to penalize hospitals, will be important. For these reasons, the AHA agrees with MAP's initial recommendation for this measure to not be supported in rulemaking.

Johnson & Johnson

Johnson & Johnson supports the recommendation of the Workgroup to not move forward with this measure for inclusion in the IQR program. We recognize the importance of hospital commitment to health equity and the role that structural measures can play as a bridge to more meaningful process and outcome measures, as well as the importance of the five attestation questions. However, an attestation of commitment is not sufficient. We encourage the development of measures that assess the degree to which health equity has been improved and social drivers that impact access to care are being addressed by hospitals.

American Medical Association

While the American Medical Association (AMA) supports the integration of health equity strategies and initiatives throughout a hospital's leadership and the entity's overall structure and practices, we do not believe that the development of a structural measure, particularly one that primarily looks for the presence of equity-focused documents, in the absence of any demonstrated linkage to improvement in patient outcomes should be pursued. This approach will likely increase administrative burden to report a measure that does not drive the improvements we all desire and would be one that will top out quickly. We encourage CMS to shift focus from developing this type of measure and target those measures, initiatives, and activities that prioritize the collection and reporting of additional relevant disparities data and promote interventions that address them. For these reasons, we support the current

recommendation of “Do Not Support.”

American Hospital Association

The AHA disagrees with the MAP’s recommendation of Do Not Support, and instead believes this measure should be re-classified as “Do Not Support with Potential for Mitigation.” While there is limited information to evaluate the potential impact of this measure on quality of care, this measure has potential for future use in CMS programs because it fills a critical gap.

Hospitals and health systems are deeply committed to the important work of improving health equity for the patients and communities they serve. The topics addressed by the questions included in the measure generally represent important actions that hospitals are taking to improve outcomes for all patients. However, the unclear logistics of reporting, calculating and publicly displaying results for this measure as currently specified may detract from its usefulness. Because the measure is so early in its development, the measure steward has not yet field tested the measure or engaged stakeholders to determine the usability, acceptability or face validity of the questions informing performance. We believe that once these activities are completed, CMS will have more information to hone the measure and consider it for use in future programs.

The additional development activity on this measure should focus on the clarity and consistency of terms used in the measure. Because the measure itself is lengthy, multi-faceted and uses terminology with definitions that could vary, it is critical for CMS to provide clear, detailed reporting guidance to ensure consistent interpretations within and across organizations. As currently written, and without guidance, we believe the measure’s meaning may be more accessible to experts in health equity than it is to other hospital staff, and even across health equity leaders, CMS may find that interpretations of terms used in the measure could vary. Clear guidance and education from CMS would be key to ensuring accurate and consistently reported information.

Another major concern relates to how performance would be calculated. According to the measure’s proposed specifications, performance would be reported as a percentage of questions out of five total to which the hospital responded affirmatively to all sub-parts of the question. Suggesting that a hospital is “40% committed to health equity” would be unhelpful – and potentially misleading -- to patients, providers, administrators, and the community. We therefore recommend that CMS reconsider how to convey to the public what hospitals and health systems are doing to demonstrate their commitment to this essential issue.

Finally, we encourage CMS to work with stakeholders to refine the wording of the questions as well as the content. For example, question 2(c) asks whether the hospital inputs information collected into “structured, interoperable data elements using CEHRT.” While we agree that CEHRT is an important tool for data collection and analysis, it is not yet clear whether CEHRT is the optimal approach to collecting and reporting health equity related data, and it is even less clear whether the infrastructure exists for those data to be “interoperable.” Question 2 also asks about the collection of “demographic and SDOH information,” which is a very large category; attesting affirmatively to this question would not provide useful information to patients or the community.

The AHA and our members are working to provide equitable and accessible care in our communities and to address and rectify disparate outcomes. We believe it is important to hold each other accountable for this work, and thus urge CMS to continue to look for ways to include this topic in its quality

measurement programs. We gladly volunteer to partner with the agency in this pursuit.

Association of American Medical Colleges (AAMC)
The Hospital MAP did not support for rulemaking the Hospital Commitment to Health Equity structural measure (MUC2021-106) for the IQR Program due to insufficient evidence on potential impact of the measure on quality. This measure assesses equity-focused organizational competencies across five questions/domains. The AAMC recommends that the MAP revise its recommendation to conditional support for rulemaking, pending NQF endorsement. We believe that the development of structural and process measures is a start to using quality measurement tools to improve health equity. Structural measures are often at the beginning stages of measuring quality for a given area or topic because they measure what is in the scope of hospital control and can be tied to the early evidence base to inform future interventions. Hospitals cannot drive equity improvements alone, but structural measures that incent equity-focused, evidence-based best practices, such as screening for health-related social needs and performing community needs assessments with community-based partners, can lead us to further development and evaluation of equity metrics that drive improvement and are inclusive of community-based partnerships.

KAREN L SMITH MD PA
Patient access to services will result in better outcome when the tertiary care system has total commitment toward provision of equitable care across the entire system.

American College of Surgeons
ACS comments to National Quality Forum (NQF) Measure Application Partnership (MAP) recommendation on MUC 2021-106: Hospital Commitment to Health Equity

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) review of the 2021-2022 recommendations for Measures Under Consideration (MUC). 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 the MAP and the Centers for Medicare and Medicaid Services (CMS) 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.

In our comments below we provide specific feedback MUC 2021-106: Hospital Commitment to Health Equity measure. We also recommend fundamental changes to the national quality measurement framework for the MAP to consider which we believe are critical for the transition toward patient-centered value-based care.

MUC 2021-106: Hospital Commitment to Health Equity

During the National Quality Forum (NQF) MAP Hospital workgroup meeting, the workgroup voted to “do not support for rulemaking” the Hospital Commitment to Health Equity measure in the Inpatient Quality Reporting (IQR) program. In our initial comments to the MAP, we provided support for this structural measure that focuses on improving health equity at the hospital level. To follow up on our initial comments, we want to express our concern regarding the NQF MAP’s review of this measure, including the discussion that followed which disregarded the value of structural measures. The MAP’s rationale

for not supporting the measure stated that, “literature does not closely link the measure to clinical outcomes and a performance gap at the individual hospital level on the specific structural elements has not been established in the literature.” Additionally, the workgroup was generally unsupportive of the measure because it was a structural measure, noting that structural measures are “check the box” measures.

In contrast, the ACS believes that structural measures are a key component to a comprehensive quality program. To ACS, a comprehensive quality program should be built around the team-based nature of patient care delivery, provide patients with the information they need to meet their health goals, and drive surgical teams toward improvements in care and a culture of excellence. To accomplish these objectives, a quality program must include components that evaluate the structures, processes, and the interdependencies that are in place and building toward patient’s goals, be informed by measurable outcomes, and incorporate patient experiences. Attestation that key structures and processes are in place can assure the right care is applied for the right indication. These components are part of ACS Quality Programs, which are referred to as verification or accreditation programs where care is verified for a specific condition by ACS.

To this end, ACS believes that the introduction of the Hospital Commitment to Health Equity measure takes a step toward moving federal quality programs forward, especially when seeking to drive hospitals toward inclusivity and health equity. It has proven difficult to reliably measure health care disparities due to current inconsistencies in demographic data collection and availability, a shortage of resources in facilities to track patients over time, and more. As CMS and other stakeholders continue to develop mechanisms to effectively measure disparities in healthcare, the ACS believes that structural measures like this serve as a good starting point to ensure that hospitals have the proper structures and processes in place to move towards a culture of inclusivity. The ACS commends CMS for developing and introducing this measure that intends to assess how a hospital promotes an organizational culture of equity-focused leadership, its commitment to robust demographic data collection, and the active review of disparities in key quality outcomes.

NQF and CMS Need New Hypothesis for the Quality Measure Enterprise

The discussion of the use of structural measures during the MAP meeting illustrates a larger issue regarding the general framework used for the driving quality in both CMS program and NQF MAP initiatives. The ACS has expressed concerns that the quality measure enterprise has operated with the hypothesis that if we use performance metrics in payment incentive programs with adequate levels of participation and hold clinicians accountable using public reports and clinical feedback, that should be enough to establish a culture of quality improvement. However, this hypothesis has fallen short of the mark; it has not accomplished what we have tried to achieve in driving high quality. Simply put, incentivizing payment using limited, unaligned performance measures is failing to achieve the intended goals.

The ACS has followed NQF and MAP proceedings for many years and is concerned that the NQF continues to apply this failed hypothesis, becoming too centered on staying within the lines of focusing on outcome measures and certain topic areas deemed high priority. From the ACS perspective, these efforts no longer align with modern healthcare processes, nor do they drive quality improvement. Truly driving improvement is more about understanding human factors and team-ness than it is about

measuring single structural elements, processes, or sporadic outcomes—at all levels of measurement (hospital, individual, etc.). It is the interrelated actions of multiple individuals which leads to clinical excellence. Isolated measures used in traditional payment incentives for accountability dilute the interrelated elements of care and shared accountability. As ACS has stated in the past, when sporadic measures are applied in a payment program and publicly reported, the results are distracting from efforts to reward physicians for delivering high-value care and does nothing to inform patients about how their goals for care will be met.

To further illustrate this point, in the current programs physicians and hospitals are rewarded or penalized based on how their performance compares with the pre-determined "cut point" or benchmark. It is important for CMS, the NQF MAP, and other stakeholders to understand that this strategy may ultimately be harming clinicians, and facilities—and ultimately patients. For example, when measuring a surgical site infection (SSI) or readmission with a "cut point" at 3 percent or 5 percent, if a hospital performs at 3.1 percent this is not statistically discernible from another hospital who performs at 2.9 percent, however, that hospital will be penalized and designated as a low performer on CMS Care Compare. Measures are not meaningful unless patients find the measures to be informative and useful for their care and care teams respond in kind by building quality improvement (QI) into their culture; measures should be judged based on the impact they have on QI to achieve value-based care.

Additionally, when this information is publicly reported, it cannot be easily interpreted by most patients. Patients undergoing joint replacement or cardiac care want their underlying condition treated and at the same time, without harms. When a patient visits with their surgeon, they lead their conversations relative to their underlying condition and their goals of care. They state what they hope to achieve more so than what they want to avoid, such as an SSI or UTI. First, they have discussions with their surgeons about how they want to walk pain free or fix their heart valve so they can breathe more easily, etc.

The ACS experience tells us patients want to know if the care team meets verification program standards for their illness and its treatments. As a patient, wouldn't you want to go to a hospital whose team has gone through a quality verification program for your illness, such as attesting the fundamental structure exists for cancer care? Patients have experienced how complex care has become and they want to know that they are cared for by a team that has come together to align structure, process, and outcome measures in a clinical domain with external review and supports to achieve patient-centered high-quality care. Publicly reporting this information will give patients the tools they need to select healthcare teams that they can trust to best meet their goals.

These structural elements are not simple 'check the box' standards. The domains of a functioning team reflect a commitment to the condition, to measuring event rates, outcomes, patient experience, inclusiveness and more. They reflect meaningful improvement activities and the functional elements of team-based interrelated and interdependencies found at the core of a culture of excellence. It may seem counterintuitive, but the NQF traditional outcome measures taken in isolation are more consistent with a 'check the box for payment purposes' than fully constructed quality verification programs.

Solution: Incentivize a Comprehensive Quality Program

The ACS sees a path forward for CMS, NQF/MAP and others to achieve the goals of providing patients

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with the necessary information about where to get care that suits their clinical needs and how to establish its affordability. As described, ACS has viewed quality in the context of evidence-based programs that demonstrate improvements in care, while measurements are key components of such programs. Based on this work, the ACS asserts we must consider a new hypothesis for the quality measure enterprise. To drive real improvements in care we must appreciate and incentivize all the components of a comprehensive quality program— high value process, structure, resources, data, event rate monitoring, patient reported outcomes.

The ACS has decades of experience developing quality programs that are based on the ACS Quality Model framework, including ACS Trauma Center Verification, Bariatric Surgery Accreditation, and the Commission on Cancer Accreditation, to name a few. These programs have a history of aligning facilities and providers for seamless, continuous, reliable, and standardized care and have demonstrated the ability to drive improvements in care, all while promoting a culture of quality. ACS programs include attributes such as demonstrable commitment to surgical quality from the C-suite; appointment of a surgical quality officer and surgical quality committee; establishment of a hospital safety culture; a formal case review process; standard surgeon onboarding, credentialing, and privileging policies; data systems organized to find problems (such as complications and inefficiencies) and fix them; evaluation of patient-reported outcomes, and so on. Each of the elements are important to achieve a culture of introspection and improvement. Key among these is committed leaders who cultivate and direct the various role players in critical review of the revelations from their data, benchmarking and steering the improvement cycles. The Hospital Commitment to Health Equity structural measure supports many of these principles.

Furthermore, this model is supported by evidence in the peer reviewed literature that patients have better outcomes if they are treated in a facility with a verified quality program/comprehensive quality framework. One example of how a comprehensive quality framework can dramatically improve clinical outcomes is the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP). The MBSAQIP standards provide guidance for facilities to build the structure that enables them to provide safe, high-quality care to all metabolic and bariatric patients. Programs seeking MBSAQIP accreditation are required to meet eight overarching standards which outline the framework for program scope and governance, facilities and equipment resources, patient care protocols, data surveillance, and more—similar to the CMS Hospital Commitment to Health Equity measure components. Accredited centers are required to enter every metabolic and bariatric procedure performed for the treatment of obesity-related diseases into the MBSAQIP Registry. The Registry collects prospective, risk-adjusted, clinically rich data based on standardized definitions. Sites receive reports from the Registry that allow them to benchmark their outcomes and compare their results with aggregate national comparison data in the system. (1) Patient-reported outcomes are tracked longitudinally. Since the conception of this program, multiple studies have been published demonstrating that specific structural processes improve patient safety in metabolic and bariatric surgery, resulting in reduced postoperative complications, lower in-hospital mortality, reduced length of stay and lower costs.(2)(3) Another study found that surgical management of complications after bariatric surgery at MBSAQIP-accredited centers is associated with greater utilization of minimally invasive techniques, shorter hospital stays, and an increased likelihood of routine home discharge.(4) In a study analyzing verified trauma centers, the overall risk of death was 25 percent lower when care was provided at a trauma center than when it was provided at a non–trauma center.(5) Again, it is so much

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more than just holding clinicians accountable to specific quality measures.

CMS and NQF may seek further input and collaboration with the ACS given our experience with regards to the crucial domains needed for inclusion in a standards-based verification of complex surgical care. All the structural elements must be present and have the proper interrelationships to be functional and deliver on the goals, in addition to ensuring that the appropriate, well-formed care team comes together to deliver the services needed. ACS' intent is for patients with surgical conditions to be able to use CMS measures to determine where to find the best, safest, and most affordable care within reach in their community. This begins with understanding that a proper, well-formed team has come together to deliver the services needed.

1. American College of Surgeons. (2019). Optimal Resources for Metabolic and Bariatric Surgery manual presents updated program standards for overweight and obese patients. Retrieved from: https://www.facs.org/media/press-releases/2019/mbsaqip071119

2. Azagury, D., Morton, J.M. (2016). Bariatric surgery outcomes in U.S. Accredited vs. non-accredited centers: A systematic review. Journal of the American College of Surgeons. 223(3), 469-477. http://www.journalacs.org/article/S1072-7515(16)30267-8/fulltext

3. Nguyen, N.T., Nguyen, B.S., Nguyen, V.Q., et al. (2015) Outcomes of bariatric surgery performed at accredited vs. nonaccredited centers. Journal of the American College of Surgeons. 215(4), 467-477.

4. Dawson, T.H., Bhutani, N., Benns, M.V., et al. (2021) Comparing patterns of care and outcomes after operative management of complications after bariatric surgery at MBSAQO accredited bariatric centers and non-bariatric facilities. Surgical Endoscopy (35), 4719-4724. https://link.springer.com/article/10.1007%2Fs00464-020-07942-5

5. MacKenzie, EJ., Rivara, FP., Jurkovich, GJ., et al. (2006). A national evaluation of the effect of trauma-center care on mortality. New England Journal of Medicine. 354(4), 366-78. https://pubmed.ncbi.nlm.nih.gov/16436768/

AHIP

On behalf of AHIP, thank you for the opportunity to comment on this measure. While we agree with MAP initial recommendation that further testing and NQF review of this measure are necessary, we believe that implementation of this measure could advance health equity. This measure could promote better collection of demographic data and monitoring for healthcare disparities. Better data and understanding of where there are deficits in quality are essential to advancing health equity. We recommend MAP change its position to conditional support pending the results of NQF endorsement.

MUC2021-122 Excess days in acute care (EDAC) after hospitalization for acute myocardial infarction (AMI)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting Program

Workgroup
Hospital

Measure Description
This measure estimates days spent in acute care within 30 days of discharge from an inpatient hospitalization for AMI. This measure is intended to capture the quality of care transitions provided to discharged patients hospitalized with AMI by collectively measuring a set of adverse acute care outcomes that can occur post-discharge: 1) emergency department (ED) visits, 2) observation stays, and 3) unplanned readmissions at any time during the 30 days post-discharge. Readmissions are classified as planned and unplanned by applying the planned readmission algorithm (PRA). Days spent in each care setting are aggregated for the 30 days post-discharge with a minimum of half-day increments.

Numerator
The outcome of the measure is a count of the number of days the patient spends in acute care within 30 days of discharge from an eligible index AMI hospitalization. We define days in acute care as days spent in an ED, admitted to an observation unit, or admitted as an unplanned readmission for any cause to a short-term acute care hospital, within 30 days from the date of discharge from the index AMI hospitalization.

Numerator Exceptions
N/A

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

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

Denominator Exclusions
The measure excludes index hospitalizations that meet any of the following exclusion criteria:

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

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2. Discharged against medical advice
3. Same-day discharges
4. AMI admissions within 30 days of discharge from a prior AMI index admission

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
Fully developed. We have attached the NQF testing attachment that provides the details of reliability and validity testing.
Please note the measure was implemented in IQR in 2018 and is being submitted now only as a refinement to the existing measure.

What is the target population of the measure?
The measure includes patients who are 65 years or older and enrolled in fee-for-service (FFS) Medicare and hospitalized in non-federal hospitals or are patients hospitalized in Veterans Health Administration (VA) facilities.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Cardiovascular disease (cardiology)

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims); Claims Data

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
Cohort determination (inclusion/exclusion criteria), risk adjustment, facility identification.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Hospital inpatient acute care facility; Veterans Health Administration facility

What one healthcare domain applies to this measure?
Seamless Care Coordination

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
2706

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Alternate Measure ID
N/A

What is the endorsement status of the measure?
Endorsed

NQF ID Number
NQF # 2881

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Other: Minimum case volume for public reporting

If not exactly as endorsed, describe the nature of the differences
The originally endorsed version of this measure had a minimum case volume of 25 admissions for the measure to be publicly reported. Due to reliability concerns, CMS has increased the minimum case volume to 50 admissions.

If endorsed: Year of most recent CDP endorsement
2017

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2022

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
Year: 2014

Measure ID : MUC14 X3728

Hospital Workgroup, 2014

Hospital Inpatient Quality Reporting

2014: Conditionally support

Conditional support pending NQF endorsement

Report Page Number: Spreadsheet of MAP 2015 Final Recommendations, row 226

Link: https:www.qualityforum.org\/WorkArea\/linkit.aspx?LinkIdentifier=id&ItemID=78711

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs
CMS has been publicly reporting this measure for the nation's non-federal short-term acute care hospitals (including Indian Health Service hospitals) and critical access hospitals since 2018. In 2020, VA hospitals were included.

What other federal programs are currently using this measure?
Hospital Inpatient Quality Reporting Program; CareCompare

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
There are several similar measures, but no competing measures.
NQF #0505: Hospital 30-day all-cause risk-standardized readmission rate (RSRR) following acute myocardial infarction (AMI) hospitalization
NQF #2880: Excess Days In Acute Care (EDAC) After Hospitalization For Heart Failure (HF)
NQF #2882: Excess Days In Acute Care (EDAC) After Hospitalization For Pneumonia

How will this measure be distinguished from other similar and/or competing measures?
This measure is specific for the cohort (AMI) and the outcome (ED visits, observation stays, readmissions). The related AMI readmission measure only captures inpatient readmission.

How will this measure add value to the CMS program?
There are no competing measures.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Please see the CMS consensus-based entity "Evidence Attachment."

Evidence that the measure can be operationalized
All the data needed to calculate the measure score are available to CMS.

The data sources for this measure include:

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

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

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

How is the measure expected to be reported to the program?
Claims

Feasibility of Data Elements
ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap
Of the 4,074 hospitals included in the measure between July 1, 2016 and June 30, 2019, the mean AMI EDAC measure score was 3.5 (SD, 26.3), with a range of -141 to 249. The 10th percentile was -23, and the 90th percentile was 33.5. The interquartile range was -11.0 to 13.1.
Out of 4,074 hospitals in the measure cohort, 255 had EDAC "fewer days than average," 1,406 were "average," and 481 had EDAC "more days than average." 1,932 were classified as "number of cases too small" (fewer than 25) to reliably tell how well the hospital is performing.

Unintended Consequences
We have not identified any unintended consequences since the implementation of the current measure. We monitor stakeholder feedback through our question and answer process and assess changes in measure scores year over year to ensure there are no unintended consequences such as the inappropriate shifting of care, increased patient morbidity and mortality, and other negative unintended consequences for patients.

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Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Between July 1, 2016 and June 30, 2019, 482,163 admissions met the cohort inclusion and exclusion criteria.

Estimate of Annual Improvement in Measure Score
To compare performance on the AMI EDAC measures across performance periods, we show the distribution of measure scores for hospitals with at least 50 admissions for Medicare FFS admissions only. We removed VA admissions as they only became part of the cohort during the most recent reporting period (2016-2019) and therefore we do not have trend information for VA admissions. Our results show that over the past three reporting periods there has been improvement in measure scores across most of the distribution.

Performance Period	Mean	Std Dev	Min	10th Pctl	20th Pctl	25th Pctl	30th Pctl	40th Pctl
July 1, 2014 – June 30, 2017	7.3	20.7	-46.6	-18.0	-9.5	-6.9	-4.3	0.3
July 1, 2015 – June 30, 2018	6.6	20.6	-45.5	-17.8	-11.0	-7.6	-5.0	0.1
July 1, 2016 – June 30, 2019	6.9	21.6	-58.7	-18.9	-10.3	-7.6	-5.4	-0.3

(table continued)

Performance Period	Median	60th Pctl	70th Pctl	75th Pctl	80th Pctl	90th Pctl	Max
July 1, 2014 – June 30, 2017	5.4	10.8	16.6	19.9	23.4	32.5	127.5
July 1, 2015 – June 30, 2018	5.0	10.2	16.0	19.0	22.8	31.5	150.4
July 1, 2016 – June 30, 2019	4.5	9.8	15.8	19.5	23.6	35.0	114.7

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

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Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patient representatives in the TEP were engaged a total of 2 times during 2 structured TEP conference calls.

Total Number of Patients and/or Caregivers Consulted
2

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
2:14

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
11

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
8

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
11

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

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Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
The AMI EDAC measure was implemented by CMS in the Inpatient Quality Reporting Program in 2018. At that time, facilities needed to have at least 25 cases for the measure to be publicly reported. This measure went through NQF Scientific Methods Panel review where the SMP voted the reliability as "does not pass" due to reliability of <0.4 with a minimum sample size of 25. CMS has therefore decided to raise the minimum case volume to 50, with a reliability of 0.402. We interpret the reliability of this measure as adequate in the context of split-sample reliability for a clinical risk-adjusted outcome measure.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Random Split Half Correlation

Reliability Testing Sample Size
4074

Reliability Testing Statistical Result

Hospitals Included for ICC calculation	Split-Sample ICC with Spearman Brown Adjustment
>=2 admissions	0.230
>=25 admissions	0.384
>=50 admissions	0.402
>=100 admissions	0.470
>=200 admissions	0.560
>=300 admissions	0.628

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
25 44.3%

Type of Validity Testing
N/A

Measure Score Validity
N/A

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Validity Testing: Type of Validity Testing Analysis

Face Validity; Other: Empirical Validity

Validity Testing Sample Size

We provide both face validity and empiric validity testing results. The sample size pertains only to the empiric validity testing results. Empirical Validity: We selected the following to use for validity testing:

1. Hospital Star Rating readmission group score (n=3,836)
2. Overall Hospital Star Rating Summary score (n=3,877)
3. AMI Readmission Measure (4,074)

Validity Testing Statistical Result

Face Validity:

We systematically assessed the face validity of the measure score as an indicator of quality by soliciting the TEP members' agreement with the following statement: "The risk-standardized acute care days obtained from the measures as specified can be used to distinguish between better and worse quality hospitals." Results of the TEP rating of agreement with the validity statement were as follows:

Rating	# of Responses (N=12)	Percent (%)
6 (strongly agree)	4	33.3%
5 (moderately agree)	6	50.0%
4 (somewhat agree)	1	8.3%
3 (somewhat disagree)	0	0.0%
2 (moderately disagree)	1	8.3%
1 (strongly disagree)	0	0.0%

Empirical Validity:

1. Correlation between AMI EDAC Scores and Hospital Star Rating Readmission Group Scores with and without AMI EDAC (Table 1A)
2. Correlation between AMI EDAC Scores and Star Ratings Summary score (Table 1A)
3. Correlation between AMI EDAC Measure Scores and domains of Hospital Consumer Assessment of Healthcare Providers and Systems (Table 2).

Table 1A: Relationship between AMI EDAC and Star Ratings

Measures Used for Validity Testing	Number of Hospitals	Pearson's Correlation with EDAC	p value
Star Rating Standardized Readmissions Group Scores	3,840	-0.380	<0.0001
Star Rating Standardized Readmission Group Scores Excluding AMI EDAC	3,840	-0.313	<0.0001
Star Rating Standardized Summary Scores	3,877	-0.247	<0.0001
Star Rating Standardized Summary Scores Using Readmission Group Scores Excluding AMI EDAC	3,877	-0.221	<0.0001

Table 2: Relationship between AMI EDAC and HCAHPS

Measures Used for Validity Testing	Number of Hospitals	Pearson's Correlation with EDAC	p value
HCAHPS Care Transition Performance Rates	2,686	-0.189	<0.0001
HCAHPS Nurse communication linear mean score	3,229	-0.213	<0.0001
HCAHPS Doctor communication linear mean score	3,229	-0.195	<0.0001
HCAHPS Staff responsiveness linear mean score	3,229	-0.208	<0.0001

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HCAHPS Discharge information linear mean score	3,229	-0.232	<0.0001

Validity Testing Interpretation of Results

Face Validity:
The validity of the measure is supported by strong face validity results, as measured by systematic feedback from the TEP. As shown the table above, 11 of 12 (91.7%) TEP members strongly, moderately, or somewhat agreed with the statement: "The risk-standardized acute care days obtained from the measures as specified can be used to distinguish between better and worse quality hospitals."

Empirical Validity Testing:
Using the recently updated Star Ratings methodology that no longer uses the latent variable model, but rather averages the performance of measures in the measure group, we compared hospitals' performances on AMI EDAC with performance on Star Ratings summary scores and Readmission Group scores, with and without the AMI EDAC measure component as part of the Star Rating calculation (Table 1A). The results show that while correlations are weaker when the AMI EDAC measure is removed from Star Ratings (-0.313 vs. -0.380 for the Readmission Group Score, and -0.221 vs. -0.247 for the Summary Score), most of the association between the domains is retained (Table 1A). Consistent with the results seen for Star Ratings, our results show an association in the hypothesized direction with components of HCAHPS (Table 2). Taken together, these results show there is a relationship in the expected strength and direction between the AMI EDAC measure and other measures that reflect outcomes and processes of care that relate conceptually to post-discharge hospital visits.

Measure performance – Type of Score

Other: Excess days in acute care (EDAC) per 100 discharges

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

For the most recent reporting period (July 1, 2016-June 30, 2019), mean performance rate and standard deviation is 3.6 excess days per 100 discharges, with a standard deviation of 26.3 for all hospitals. For hospitals with at least 50 admissions, the mean performance rate and standard deviation for the most recent reporting period is 6.9 per 100 discharges, with a standard deviation of 22.

Benchmark, if applicable

N/A

Measure Contact Information

Measure Steward

Centers for Medicare and Medicaid Services

Measure Steward Contact Information

James Poyer
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Long-Term Measure Steward

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N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

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N/A

Section 2: Preliminary Analysis – MUC2021-122 Excess days in acute care (EDAC) after hospitalization for acute myocardial infarction (AMI)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: The Measure Under Consideration is currently included in the Hospital IQR Program, alongside two other measures of Excess Days in Acute Care after Hospitalization (for heart failure and pneumonia), and a measure of Hospital-Wide All-Cause Unplanned Readmissions. Note that this update raises the minimum threshold of AMI admissions before a measure score can be calculated, from 25 to 50 – no other values were changed. Thus, the measure adds unique value to the measure set both in the clinical condition focus, and in the inclusion of both ED visits and observation stays, going beyond readmissions only. The measure falls under the Admissions and Readmissions to Hospitals Meaningful Measure Area, and as a care coordination measure, is a high priority for the IQR program itself.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: The clinical outcome captured in this measure is days in acute care, including ED visits, readmissions, and observation stays. Days in acute care are a salient metric for patients, as these represent the experience of an adverse event and associated cost of the hospital visit. There are several randomized controlled trials showing that hospitals can implement interventions to reduce readmissions in patients after hospitalization for AMI and heart failure, including a home visit and telephone check-in program (Carroll et al, 2007), and a program designed to promote adherence to treatment guidelines (Carlhed et al, 2009). 11 of 12 members of a Technical Expert Panel (TEP) agreed that the measure could be used to distinguish between better or worse quality hospitals, and empirical validity testing shows a relationship between this measure's result and other measures of both processes and outcomes related to post-hospitalization acute care visits.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Acute myocardial infarction (AMI) is a common, and costly, condition: billings for AMI represent 3.8% of all Medicare costs, and 2.5% of total hospital stays (Torio et al, 2016). A performance gap in this measure's result has been observed in the five years since the measure was first

implemented. In 2016-2019, the performance ranged from -58.7 to 114.7 excess days, with a median of 4.5 and standard deviation of 21.6. The 20th percentile of hospitals performed at -10.3 days, and the 80th percentile at 23.6 days, indicating that these results were not driven by extreme outliers, but instead show a substantial range of performance across the sample. Performance between hospitals also differed based on the facilities' proportion of SES patients; the median performance for hospitals in the first quartile of SES patient proportion was -.5 days, whereas the fourth quartile performance median performance was 9.8 excess days, according to latest performance data submitted to NQF.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: The measure is already included in the Hospital IQR Program. There are two measures in the program that are similar; a measure of all-cause unplanned readmissions, and a measure of the total cost of an AMI episode of care. This measure distinguishes itself from the readmissions measure by going beyond unplanned readmissions by capturing ED visits and observation stays, and by its specific focus on AMI; from the total cost of care measure by focus on the specific clinical outcomes associated with an AMI hospitalization.

The condition-specific focus on AMI is consistent with the approach of other CMS hospital quality programs; the Hospital Readmissions Reduction Program (HRRP) includes a measure of readmissions after AMI hospitalization, and the Hospital Value-Based Purchasing Program (HVBP) includes a measure of mortality after AMI hospitalization.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: All data elements are available in electronic sources, and in defined fields with no manual abstraction required. The measure has been successfully operationalized in the Hospital IQR Program for nearly six years.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: The measure was endorsed by NQF in 2016, for a care setting, level of analysis, and denominator population consistent with that of the IQR program. In a 2021 review for maintenance of endorsement, NQF's Scientific Methods Panel did not pass the measure, basing their decision on the low reliability of the measure score for hospitals with fewer than 50 admissions for AMI. This measure has subsequently been updated to exclude hospitals with fewer than 50 admissions, yielding a split-sample intraclass correlation coefficient of 0.4 for included hospitals, a statistic generally indicating moderate reliability.

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?

Yes/No: No

Justification and Notes: After nearly six years of stakeholder feedback after measure implementation in IQR, no negative unintended consequences were identified. No unintended consequences were identified in public comments during the measure's Consensus Development Process (CDP) review in 2017.

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MAP Rural Health Advisory Group Input:

Relative priority/utility:

- Some raised concern that this measure is not rural relevant as most patients are transferred to other facilities for treatment or are treated in the outpatient setting.

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.

Average: 3.7
1 – 0 votes
2 – 2 votes
3 – 2 votes
4 – 11 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- There was some concern with misaligned incentives with this measure

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity

Average: 3.3
1 – 0 votes
2 – 2 votes
3 – 9 votes
4 – 7 votes
5 – 0 votes

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Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

Summary: What is the potential value to the program measure set?

The Measure Under Consideration totals the ED visits, observation stays, and readmissions for patients 30 days after discharge from inpatient care following Acute Myocardial Infarction (AMI). The measure is currently included in the IQR program; the measure under consideration updates the minimum admissions threshold, strengthening the reliability of the measure result. This measure distinguishes itself both for its condition specificity, and the inclusion of other health care visits beyond hospital readmissions.

Summary: What is the potential impact of this measure on quality of care for patients?

Nearly four percent of all Medicare costs are attributable to AMI hospitalizations, an indicator of the prevalence and impact of this clinical condition. Hospital performance in treating and discharging patients with AMI varies considerably, with the outliers yielded hundreds of excess days in acute care for patients relative to their peers. Widespread improvement on this measure would have a significant impact on both costs to the health care system, and the number of patients experiencing unplanned hospital visits.

Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) appreciates that the Centers for Medicare and Medicaid Services was responsive to the concerns of the National Quality Forum's Scientific Methods Panel and increased the case minimum to 50 patients to improve the intraclass correlation coefficients (ICC) result. The FAH believes that measures must meet a minimum ICC reliability threshold of 0.6 or higher. Based on the information submitted, it would require at least 300 patients before this threshold could be achieved and therefore would limit the number of hospitals on which the measure could be reported. As a result, the FAH does not believe that this measure is appropriate for accountability programs and requests that the highest level of MAP recommendation be "Do Not Support."

American Medical Association

The American Medical Association (AMA) appreciates the Centers for Medicare and Medicaid Services' efforts to ensure that this measure produces reliable performance scores. Even with the increase of cases to a minimum of 50, we do not believe that the measure meets what we consider to be the acceptable interclass correlation coefficients threshold of 0.6. Because the minimum number of cases that would be required to achieve this threshold is 300, we anticipate that it will significantly reduce the number of hospitals to which the measure would apply. As a result, the AMA does not believe that the measure is appropriate for this program and recommends that the highest level of MAP recommendation be "Do Not Support."

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Premier, Inc.
Premier does not support inclusion of this measure. The measure combines readmissions, observation stays and ED visits into a single number of days; each of these settings reflect widely different approaches to patient-centered care and cannot be interpreted from a single number. Moreover, CMS already includes measures that address readmissions, as well as cost of care (MSPB). Adoption of this measure will duplicate these measures and add little value to the measure set.

American Heart Association
The AHA urges the MAP to consider the unique circumstances that providers such as large hospitals face that might pose challenges to timely discharge. For example, the COVID-19 pandemic has presented novel circumstances that might extend the length of a patient's stay. Large hospitals for instance, who are otherwise ready to discharge a patient to another healthcare setting (e.g., a skilled nursing facility), are constrained by the inability of other health care settings to promptly accept patients due to concerns related to the pandemic.

Also, the MUC list documentation mentions that there will be significant changes to this measure. However, we are unable to provide comments on those changes since the specification changes have not been made available. Therefore, the AHA does not support the MAP's recommendation to support this measure for rulemaking.

American Medical Association
The American Medical Association (AMA) continues to be concerned that the measure does not meet what we consider to be the acceptable interclass correlation coefficients threshold of 0.6. Because the minimum number of cases that would be required to achieve this threshold is 300, we anticipate that it will significantly reduce the number of hospitals to which the measure would apply. As a result, the AMA does not believe that the measure is appropriate for this program and recommends that the highest level of MAP recommendation be "Do Not Support."

American Hospital Association
The AHA is generally supportive of the MAP's recommendation because the revision to the measure's specifications improve its reliability. However, we remain skeptical about the overall value of this measure, and encourage CMS to consider removing it from the IQR in the future.

While excess days measures are ostensibly constructed to avoid providers discouraging care that would affect their readmissions outcomes, the results have been inconsistent. Studies by MedPAC have suggested that falling readmissions rates are not offset by increases in the use of observation stays and ED visits, which undermines the justification for the use of excess days measures. Additionally, these measures frame any interaction with the acute care system as negative, when there are often appropriate reasons for a patient to visit the ED or stay in observation.

In addition, this measure is developed and specified very similarly to readmissions measures used in CMS programs, but performance is calculated differently; in essence, the same inputs are used to achieve different results.

The proposed revision to the specifications of this measure would increase the minimum case volume for public reporting from 25 to 50 due to reliability concerns. However, even with this change, the measure still barely clears moderate reliability. Because of these logistical and conceptual concerns, the

Excess Days for AMI measure is not a reliable, accurate indicator of quality and should not be included in a quality reporting program.

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MUC2021-084 Hospital Harm – Opioid-Related Adverse Events

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting (IQR) Program, Medicare Promoting Interoperability Program for Hospitals

Workgroup
Hospital

Measure Description
This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

Numerator
Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.

Numerator Exceptions
N/A

Denominator
Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.

Denominator Exclusions
N/A; there are no denominator exclusions

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
N/A

What is the target population of the measure?
All Payer

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Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Other: Not specialty specific

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Electronic Health Record

If applicable, specify the data source
N/A

If EHR 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?
Community hospital; Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
6032

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Submitted

NQF ID Number
NQF # 3501e

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

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If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
Yes

If eCQM, enter Measure Authoring Tool (MAT) number
819

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
Yes

If eCQM, does any electronic health record (EHR) system tested need to be modified?
Yes

If yes, how would you describe the degree of effort?
4

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
Year: 2017

Measure ID: MUC17-210

Workgroups: NQF MAP Hospital Workgroup December 2017

Program: 2017- Hospital Inpatient Quality Reporting Program

Recommendation: 2017- Refine and resubmit

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MAP noted that this measure concept assesses a critical patient safety issue that should be addressed with urgency. However, MAP raised concerns that the measure has not been tested in enough hospitals to assess measure reliability and validity across facilities, and noted that further testing should be completed before it is implemented in the program. As the measure developer completes testing of the measure, MAP requested that the developer consider the impact of chronic opioid users and patients receiving Suboxone (buprenorphine and naloxone). MAP noted that the completed testing should demonstrate reliability and validity before the measure is submitted to NQF for review and endorsement. MAP recommended that the Patient Safety Standing Committee pay special attention to potential unintended consequences and noted there may be a need to balance this measure with measures assessing appropriate use of naloxone and adequate pain control.

Report Page Number: MAP 2018 Considerations for Implementing Measures in Federal Programs: Hospitals, page 9

What is the history or background for including this measure on the new measures under consideration list?

Measure previously submitted to MAP, refined and resubmitted per MAP recommendation

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

NQF #3389: Concurrent Use of Opioids and Benzodiazepines (COB)

NQF #3316e: Safe Use of Opioids- Concurrent Prescribing

How will this measure be distinguished from other similar and/or competing measures?

The Hospital Harm – Opioid-Related Adverse Events eCQM, the Safe Use of Opioids – Concurrent Prescribing Measure (NQF #3316e), and the Concurrent Use of Opioids and Benzodiazepines (NQF #3389) all have the same general target population, which are adult patients who receive opioids. However, the focus of each measure is very different. The Hospital Harm – Opioid-Related Adverse Events eCQM focuses on patients who receive excessive doses of opioids during their hospitalization and, subsequently, require naloxone to prevent further patient harm. In contrast, NQF #3316e focuses on patients who receive concurrent opioid or opioid and benzodiazepine prescriptions at discharge, putting them at risk of adverse drug events after hospital discharge, and NQF #3389 tracks concurrent opioid and benzodiazepine outpatient prescriptions. As a result of the varying measure focuses, the Hospital Harm – Opioid-Related Adverse Events eCQM has a broad denominator of all inpatient adults >18 years who received a hospital administered opioid, while NQF #3316e has a more narrow denominator of adults >18 years prescribed an opioid or benzodiazepine at discharge from a hospital-based encounter. NQF #3316e also excludes patients with an active cancer diagnosis, palliative care order, or length of stay >120 days. NQF #3389 addresses outpatient prescription claims and excludes patients in hospice, or with cancer or sickle cell disease diagnosis.

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How will this measure add value to the CMS program?

The Hospital Harm – Opioid Related Adverse Events eCQM focuses on patients who receive excessive doses of opioids during their hospitalization and, subsequently, require naloxone to prevent further patient harm. This approach will complement the similar other measures in place that focus on the outpatient population.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Opioids are often the foundation for sedation and pain relief. However, use of opioids can also lead to serious adverse events, including constipation, oversedation, delirium, and respiratory depression. Opioid-related adverse events have both patient-level and financial implications. Patients who experience this event have been noted to have 55% longer lengths of stay, 47% higher costs, 36% higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events (Kessler et al., 2013).

Most opioid-related adverse events are preventable. Of the adverse drug events reported to the Joint Commission´s Sentinel Event database, 47% were due to a wrong medication dose, 29% to improper monitoring, and 11% to other causes (e. g., medication interactions, drug reactions) (Joint Commission, 2012; Overdyk, 2009). Additionally, in a closed-claims analysis, 97% of adverse events were judged preventable with better monitoring and response (Lee et al., 2015). Naloxone administration is often used as an indicator of a severe opioid-related adverse event, and implementation of this measure can advance safe use of opioids in hospitals and prevent these serious and potentially lethal adverse drug events. Naloxone is an opioid reversal agent typically used for severe opioid-related adverse events. Naloxone administration has been used in a number of studies as an indicator of opioid-related adverse events (Nwulu et al., 2013; Eckstrand et al., 2009).

From Part 10 of the 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Lavonas et al., 2015), the following recommendation is listed for use of Naloxone :

Naloxone is a potent opioid receptor antagonist in the brain, spinal cord, and gastrointestinal system. Naloxone has an excellent safety profile and can rapidly reverse central nervous system (CNS) and respiratory depression in a patient with an opioid-associated resuscitative emergency.

References:

Eckstrand, J. A., Habib, A. S., Williamson, A., Horvath, M. M., Gattis, K. G., Cozart, H., & Ferranti, J. Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009;3(1), 18.

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Kessler ER, Shah M, Gruschkus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy. 2013;33(4):383-391.

Lavonas EJ, Drennan IR, Gabrielli A, Heffner AC, Hoyte CO, Orkin AM, Sawyer KN, Donnino MW. Part 10: Special Circumstances of Resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015 Nov 3;132(18 Suppl 2):S501-18. doi: 10.1161/CIR.0000000000000264. Erratum in: Circulation. 2016 Aug 30;134(9):e122.

Lee, L. A., Caplan, R. A., Stephens, L. S., Posner, K. L., Terman, G. W., Voepel-Lewis, T., & Domino, K. B. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015:122(3), 659-665.

Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S. E., & Coleman, J. J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. Eur J Clin Pharmacol. 2013;69(2), 255-259.

Overdyk FJ: Postoperative respiratory depression and opioids. Initiatives in Safe Patient Care, Saxe Healthcare Communications, 2009 The Joint Commission. Safe use of opioids in hospitals. Sentinel Event Alert. 2012(49):1-5. https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84

For additional evidence please see the ORAE evidence attachment.

Evidence that the measure can be operationalized

This is an eCQM that uses all data elements from defined fields in the EHR. Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the OR rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs. For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction. Test sites' decisions to document opioid administration inside of the OR on paper can be driven by many factors, one of which is a workflow preference. Since all hospital-based EHR vendor systems offer anesthesia modules, there should be no technical limitation in transitioning paper-based documentation to electronic documentation. Given that non-anesthesia-related opioid administrations are already captured electronically, we are optimistic that measure implementation is still feasible. Moreover, measure implementation will drive workflow changes toward electronic capture within the OR.

How is the measure expected to be reported to the program?

eCQM

Feasibility of Data Elements

ALL data elements are in defined fields in electronic health records (EHRs)

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Evidence of Performance Gap

The rate of ORAE estimated using the patient EHR data from calendar year 2019 were within the range of harm rates found in the literature, which was between 0.1% and 1.3% among studies using naloxone administration as a surrogate measure of respiratory depression (Cashman, 2004). The relatively wide variability in the rate of ORAE across the six sites demonstrates that there exists room for improvement in reducing the ORAE among at-risk patients.

ORAE measure performance rates ranged from 0.11% (for every 1,000 qualified hospital admissions there are 1.1 inpatient encounters where patients suffered ORAE) to 0.45% (for every 1,000 qualified hospital admissions there are 4.5 inpatient encounters where patients suffered ORAE), indicating ample room for quality improvement in hospital inpatient environment. Also, larger hospitals (e.g., test sites 4 to 6), though having more numerator admissions, do not necessarily have higher ORAE rates. This suggests that all hospitals, irrespective of size, need to follow best practices in patient care to prevent ORAE.

Reference:

Cashman, J. N., and S. J. Dolin. "Respiratory and haemodynamic effects of acute postoperative pain management: evidence from published data." British Journal of Anaesthesia 93, no. 2 (2004): 212-223.

For more information see ORAE MIF and ORAE Evidence Attachment.

Unintended Consequences

We did not identify any unintended consequences during eCQM development or testing. However, CMS is committed to monitoring this eCQM's use and assessing potential unintended consequences over time, such as the inappropriate shifting of care and other negative unintended consequences for patients. However, it is important that the eCQM, as currently specified, does not detect false positives. To verify this, we conducted empirical tests to examine whether numerator cases identified by the measure are true positives. In the chart review (or parallel-form comparison) process we instructed clinical abstractors to extract both indications for and patient subsequent responses to the naloxone administration. We found that the predominant rationale for subsequent naloxone administration was that patients were somnolent or unresponsive, with the second mostly cited reason being opiate reversal. In terms of patient responses to naloxone administration, we found that the most frequently documented was: patient showed clear signs of response to naloxone administration. This qualitative evidence solidifies the evaluation of measure logic and suggests that the measure can correctly predict a true positive.

Outline the clinical guidelines supporting this measure

Two evidence-based guidelines directly support the measure focus as follows.

Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs. 2020 Feb;21(1):7-25. Epub 2019 Jul 31.

O This guideline is evidence-based and recommends that clinicians recognize that all hospitalized patients receiving systemic (e.g., transdermal, IV, oral) or neuraxial opioids for acute pain management are at risk of opioid-induced unintended advancing sedation and opioid-induced respiratory depression.

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- The panel also recommended that all patients who will receive opioids undergo a comprehensive assessment of level of individual risk before initiation of opioid therapy. Ongoing reassessment of risk that continues through the trajectory of clinical care is essential (strong recommendation, moderate level evidence).
- The panel recommends that clinicians employ evidence-based pain management that incorporates opioid-sparing and multimodal analgesia therapies (strong recommendation, high-level evidence)
- Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535-52.
- This guideline is evidence-based and recommends identification of patients with risk factors for respiratory depression includes conducting a focused history (e.g., reviewing medical records) and physical examination;
- Prevention of respiratory depression includes consideration of noninvasive positive pressure ventilation and drug selection.
- Monitoring all patients receiving neuraxial opioids for adequacy of ventilation (e.g., respiratory rate, depth of respiration [assessed without disturbing a sleeping patient]), oxygenation (e.g., pulse oximetry when appropriate), and level of consciousness.
- Increased monitoring (e.g., intensity, duration, or additional methods of monitoring) may be warranted for patients at increased risk of respiratory depression (e.g., unstable medical condition, obesity, obstructive sleep apnea, concomitant administration of opioid analgesics or hypnotics by other routes, extremes of age).

For additional information see the detailed ORAE Evidence Attachment.

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
American Society of Anesthesiologists, American Society for Pain Management

If yes, what was the grade?
Strong recommendation, high evidence

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
N/A

Type of Evidence to Support the Measure
Clinical Guidelines; Empirical data

Is the measure risk adjusted, stratified, or both?
None

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Are social determinants of health built into the risk adjustment model?
N/A

Estimated Cost Avoided by the Measure
N/A

Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
None

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patient/ caregivers were engaged a total of three times. Once during conceptualization and twice at the conclusion of specification.

Total Number of Patients and/or Caregivers Consulted
2

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:5

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

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If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
5

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
5

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
23

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
11

Measure Testing Details

Reliability Testing Interpretation of Results
The results suggest that all critical data elements are reliably and consistently captured in patient EHRs and that there is a strong concordance between data extracted from the EHR electronically and the data extracted from patient medical records manually (“gold standard”).

Type of Reliability Testing
Data Element Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise; IRR (Inter-rater reliability);Other: frequency of missing or erroneous data for critical data

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elements

Reliability Testing Sample Size
6 test sites

Reliability Testing Statistical Result
Cohen's Kappa coefficient was calculated for all 5 critical data elements for each of the six test sites. The Kappa coefficients across 5 of the 6 test sites were 1 for all of the critical data elements. For the 5th test site, two of the data elements had a Kappa coefficient of .98.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity; Predictive Validity

Validity Testing Sample Size
100 qualified admissions for each of the six implementation test sites.

Validity Testing Statistical Result
See Tables 8 -14 and Figures 2 and 3 in section 2b1.3 of the ORAE NQF Testing Attachment document.

Validity Testing Interpretation of Results
Data Element Validity

Across the six implementation test sites, all but two data elements showed a match rate of 100%, indicating that valid and accurate data were extracted from patient EHRs. The exceptions in test site 5 were due to a documentation preference. As we discussed in section 2b1.3, across the 155 (49 + 56 + 50) denominator-only cases from test sites 4 to 6 who share the same documentation pattern inside of the OR, we found only one misaligned case. The low false-negative rate provides some degree of confidence that the issue is not widely seen in the harm event the current measure seeks to identify. Moreover, for hospitals that utilize eMARs throughout, this misalignment will be eliminated. Because all hospital-based EHR vendor systems offer anesthesia modules that can document medication electronically, there should be no technical limitation in transitioning from paper-based documentation to electronic documentation.

Measure Score Validity

Across the six implementation test sites, PPV is 100%, suggesting that in all cases the qualified admissions have met the criteria for an ORAE in both the chart-abstracted and EHR-extracted data.

Sensitivity is 100% in all but one test site. This means that the probability of EHR detecting an ORAE in patients who had a true ORAE is close to 100%. Similarly, NPV is 100% in all but one test site. This

suggests that the probability of EHR detecting an at-risk patient was also a patient at risk for ORAE based on the abstracted data is near perfect. Specificity is 100% in all test sites, indicating that the probability of correctly classifying an at-risk patient when the patient is truly and solely at risk for ORAE is 100%.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
In testing, the measure performance rates ranged from 0.11% (for every 1,000 qualified hospital admissions there are 1.1 inpatient encounters where patients suffered ORAE) to 0.45% (for every 1,000 qualified hospital admissions there are 4.5 inpatient encounters where patients suffered ORAE), indicating ample room for quality improvement in hospital inpatient environment. Standard deviations ranged from 3.30% to 6.71%.

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
Centers for Medicare & Medicaid Services

Measure Steward Contact Information
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Long-Term Measure Steward Contact Information
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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-122 Hospital Harm - Opioid-Related Adverse Events

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure focuses on identifying a serious reportable event for safety and addresses the Hospital IQR Program priority area of "outcome eCQMs". The measure is fully developed, does not impose any burden to patients, and focuses on opioid-related adverse events.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is an outcome measure that calculates the proportion of inpatient events in which patients receiving opioid medications suffer an ORAE that must be addressed with an opioid antagonist (naloxone) within 12 hours following the administration of the medication. ORAEs may be prevented or reduced with the use of appropriate pain management techniques, education and training, and patient monitoring (Premier Safety Institute, 2021; The Joint Commission, 2012). The administration of opioid antagonists has been used as an identification method for ORAEs (Nwulu et al., 2012; Shafi et al., 2018).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: The measure addresses serious reportable events (ORAEs). Opioids have been identified among the drugs most commonly associated with adverse drug events (The Joint Commission, 2012) and ORAEs are associated with increased hospital costs, length of stay, readmissions, and mortality (Kessler et al., 2013; Shafi et al., 2018). The developer notes that the rate of ORAE across testing sites ranged from 0.11 to 0.45 percent. The NQF Patient Safety Standing Committee acknowledged the four-fold differences across the six sites tested. However, the Standing Committee did express concern with the low absolute measure rate. The Standing Committee also questioned whether the low number of events showed differences across sites. The measure developers identified variability in performance by age, sex, race, ethnicity, and payer source, which following national implementation of the measure may uncover additional performance gaps among vulnerable populations. Additionally, this four-fold variation equates to 60,000 patients harmed annually. The NQF Standing Committee ultimately recommended the measure for endorsement.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: While the developer has identified two existing measures that address opioid

medication prescriptions (NQF #3389 and NQF #3316e), the Hospital IQR Program does not have a measure that addresses ORAEs during an inpatient visit. NQF #3316e addresses concurrent opioid/opioid and benzodiazepine prescriptions at discharge and in the Hospital IQR Program and Medicare Promoting Interoperability Program for Hospitals, while NQF#3389 measures the percentage of patients with concurrent opioid and benzodiazepine prescriptions and is not active in any Medicare program.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The eCQM is fully specified, and the developer notes that all required data elements are readily available in electronic health records. The developer conducted feasibility testing and a provider workflow analysis and found that no adjustments were required to provider workflow to report the data. Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the operating room (OR) rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs, and they are therefore excluded from the measure numerator. For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction. Noting this consideration, the measure passed feasibility criteria for the Patient Safety Standing CDP Committee when reviewed in the Spring 2021 review cycle.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital and acute care settings. This measure was previously submitted for endorsement review in spring 2019 and was substantially updated since the initial submission. The measure has been re-submitted with updated specifications for endorsement review by the NQF Patient Safety Standing Committee in the Consensus Development Process (CDP) Spring Cycle 2021 and passed criteria for scientific acceptability.

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?

Yes/No: N/A

Justification and Notes: This measure is not currently in use and no unintended consequences were identified by the developer during testing. The developer conducted additional testing to verify that the measure would not detect false positives.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

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Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- This is a good measure and no adverse effect/issues on rural institutions

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.

Average: 4.2
1 – 0 votes
2 – 0 votes
3 – 0 votes
4 – 11 votes
5 – 3 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- Lower-resourced hospitals may have some disadvantage. Consider the inequity from a system perspective and not from the patient-perspective.
- This is a great quality measure, but not sure there is an equity component here.

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity

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Average: 3.2
1 – 0 votes
2 – 3 votes
3 – 12 votes
4 – 5 votes
5 – 1 votes

Recommendation

Preliminary Analysis Recommendation:
Support for Rulemaking

Summary: What is the potential value to the program measure set?
This fully developed and specified measure addresses a critical and preventable safety event in the Hospital IQR Program. The program does not currently include a measure that addresses ORAEs and subsequent administration of naloxone in the inpatient setting. The measure was submitted for endorsement review to the Patient Safety Standing Committee, Spring Cycle 2021 and received NQF endorsement. The measure is recommended for support based on NQF review and endorsement.

Summary: What is the potential impact of this measure on quality of care for patients?
This measure identifies hospital inpatient opioid-related adverse events (ORAEs) in which patients are administered an opioid antagonist (naloxone) within 12 hours. Opioids have been identified among the drugs most commonly associated with adverse drug events, and ORAEs may be preventable with appropriate medication management, education and training, and patient monitoring. The measure has been reviewed for NQF endorsement by the Patient Safety Standing Committee and the decision has been upheld by NQF CSAC.

Section 3: Public Comments

Federation of American Hospitals
The Federation of American Hospitals (FAH) supports addressing important patient safety concerns during an inpatient stay but questions whether this measure demonstrates a sufficient performance gap to support its use in the Hospital Inpatient Quality Reporting Program. The recent submission to the National Quality Forum reported performance scores across six hospitals that ranged between 0.11 to 0.45%.

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 vendor systems and six hospitals should not be considered sufficient. Electronic clinical quality measures (eCQMs) require significant resources and time for hospitals to implement and only those eCQMs with demonstrated gaps in care should be implemented. As a result, the FAH requests that

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the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

American Medical Association

The American Medical Association (AMA) questions whether this measure has a sufficient variation and performance gap to support its use for accountability purposes. The recent submission to the National Quality Forum reported performance scores across six hospitals that ranged between 0.11 to 0.45%. As a result, the AMA does not believe that this measure will provide meaningful data to hospitals and patients and requests that the highest level of MAP recommendation be “Do Not Support.”

Premier, Inc.

Premier supports adoption of this measure, but recommends that CMS not more forward with it until it receives endorsement. We also recommend that CMS continue to evaluate the measure as part of the IQR program before considering it for adoption into a pay-for-performance program.

American Medical Association

The American Medical Association (AMA) continues to question whether this measure has a sufficient variation and performance gap to support its use for accountability purposes. The recent submission to the National Quality Forum reported performance scores across six hospitals that ranged between 0.11 to 0.45%. As a result, the AMA does not believe that this measure will provide meaningful data to hospitals and patients and requests that the highest level of MAP recommendation be “Do Not Support.”

American Society of Anesthesiologists

ASA supports the recommendation of the MAP to include this measure in future rulemaking so long as the measure developer takes into account locations where opioids may be administered as part of a procedure in a non-operating room setting. It is our understanding that this measure tracks naloxone use in the hospital for patients receiving opioids unrelated to procedures. Recent patient safety advances in anesthesia care as well as greater access to outpatient procedure environments have allowed more patients to receive care in non-operating room anesthetizing locations. Therefore, we believe the measure developer can and should implement appropriate exclusions (e.g. operating room setting, non-operating room anesthetizing locations) within the measure.

Intermountain Healthcare

Intermountain has concerns about adopting this measure in the IQR program because of a lack of clarity regarding burden of manual data collection. Intermountain also has some concern (also noted on MUC21-084 Interoperability) about how the data will be collected and harmonized across workflows to avoid divergence of the outcomes of the measure across the IQR and Interoperability measure sets. Intermountain believes there will be considerable value in the measure for improving patient care if launched in a way to avoid excessive burden and preserve integrity across data collection methodology. Intermountain also would add that the measure should specifically exclude naloxone administration episodes via IV drip for itching. Also request clarification of how events in post-anesthesia care units and post-operative recovery units would be included/excluded from the measure.

MUC2021-118 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting (IQR) Program, Hospital Value-Based Purchasing (VBP) Program

Workgroup
Hospital

Measure Description
The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and/or TKA. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post-date of the index admission (the admission included in the measure cohort).

Numerator
The outcome for this measure is any complication occurring during the index admission [not coded present on admission (POA)] to 90 days post-date of the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes."

We are updating this measure to include 26 additional clinically vetted mechanical complication ICD-10 codes.

Numerator Exceptions
N/A

Denominator
The target population for the publicly reported measure includes admissions for Medicare FFS beneficiaries who are at least 65 years, undergoing elective primary THA and/or TKA procedures.

The measure cohort includes admissions to non-federal, short-stay, acute-care hospitals for Medicare FFS patients aged 65 years and older with a qualifying THA/TKA procedure, not transferred in from another facility. To be included in the measure cohort used in public reporting, patients must meet the following additional inclusion criteria:

1. Enrolled in Medicare fee-for-service (FFS) Part A and Part B for the 12 months prior to the date of admission; and enrolled in Part A during the index admission;

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2. Aged 65 or older
3. Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

- Fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields on the index admission claim (Note: Periprosthetic fractures must be additionally coded as present on admission [POA] in order to disqualify a THA/TKA from cohort inclusion, unless exempt from POA reporting.);

- A concurrent partial hip or knee arthroplasty procedure;

- A concurrent revision, resurfacing, or implanted device/prosthesis removal procedure;

- Mechanical complication coded in the principal discharge diagnosis field on the index admission claim;

- Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim; or,

- Transfer from another acute care facility for the THA/TKA.

Patients are eligible for inclusion in the denominator if they had an elective primary THA and/or a TKA AND had continuous enrollment in Part A and Part B Medicare fee-for-service (FFS) 12 months prior to the date of index admission.

Denominator Exclusions

The hip/knee complication measure excludes index admissions for patients:

1. Without at least 90 days post-discharge enrollment in Medicare FFS;
2. Discharged against medical advice (AMA); or,
3. Who had more than two THA/TKA procedure codes during the index hospitalization.

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

This measure is fully developed. We are bringing an updated version of this measure back to the MAP at this time due to the addition of 26 mechanical complication ICD-10 codes, a change that was clinically vetted.

The measure underwent reliability and validity testing at the facility-level during NQF endorsement maintenance in 2020; that version of the measure does not include these additional codes. All results provided in this row are from the prior version of the measure, however we do not anticipate any problems with reliability or validity with the addition of the new codes.

Implemented version of measure: Measure Score Reliability

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We estimated the overall measure score reliability by calculating the intra-class correlation coefficient (ICC) using a split sample (in other words, test-retest) method.

Split Sample Reliability: As a metric of agreement, we calculated the ICC for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSCR for each hospital was 0.524, demonstrating moderate reliability.

Facility-level Reliability

Signal to noise: Using the approach used by Adams et. al. and Yu et al., we obtained the median signal-to-noise reliability score of 0.87, which demonstrates “almost perfect” agreement.
We assessed measure score validity by comparing hospitals’ overall Star Rating with their RSCRs/ We predicted the THA/TKA complication measure scores would have a small association with the overall hospital star rating scores, with lower RSCRs associated with better Star ratings. Results: The correlation between THA/TKA complications and Star-Rating summary score is -0.185, which suggests that hospitals with lower THA/TKA RSCRs are more likely to have higher Star-Rating summary scores especially at the extremes.

We also assessed validity of the measure by examining the relationship between volume and the measure score for hospitals. We expect scores to be correlated with case volume at the hospital level. Results: There is a general trend that high volume hospitals (those in the upper deciles) have lower RSCRs than hospitals in other volume deciles.

Measure Score Validity: Validity Indicated by Established Measure Development Guidelines
We developed this measure in consultation with national guidelines for publicly reported outcomes measures, with outside experts, and with the public. The measure is consistent with the technical approach to outcomes measurement set forth in NQF guidance for outcomes measures, CMS Measure Management System (MMS) guidance, and the guidance articulated in the American Heart Association scientific statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes” (Krumholz, Brindis, et al. 2006; NQF 2010).

Data Element Validity: Validity of Claims-Based Measures
Our team has demonstrated for a number of prior measures the validity of claims-based measures for profiling hospitals by comparing either the measure results or individual data elements against medical records. CMS validated the six NQF-endorsed, claim-based measures currently in public reporting (AMI, heart failure, and pneumonia mortality and readmission) with models that used medical record-abstracted data for risk adjustment. Specifically, claims model validation was conducted by building comparable models using abstracted medical record data for risk adjustment for heart failure patients (National Heart Failure data), AMI patients (Cooperative Cardiovascular Project data) and pneumonia patients (National Pneumonia Project dataset). When both models were applied to the same patient population, the hospital risk-standardized rates estimated using the claims-based risk-adjustment models had a high level of agreement with the results based on the medical record model, thus supporting the use of the claims-based models for public reporting. Our group has reported these findings in the peer-reviewed literature (Krumholz et al. 2006; Krumholz et al. 2011; Krumholz et al. 2006a; Keenan et al. 2008; Bratzler 2011; Lindenauer 2011).

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Validity was also assessed by the TEP. The TEP supported the final measure.

Measure validity is also ensured through the processes employed during development, including regular expert and clinical input, and modeling methodologies with demonstrated validity in claims-based measures.

What is the target population of the measure?
The target population includes Medicare fee-for-service (FFS) patients aged 65 years or older undergoing THA/TKA.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Orthopedic surgery

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?

Enrollment Data; Claims Data

If applicable, specify the data source
N/A

If EHR 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 one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
0844

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Endorsed

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NQF ID Number
NQF# 1550

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Numerator

If not exactly as endorsed, describe the nature of the differences
The measure was updated to include 26 new codes for mechanical complications:

M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate

M96.661 Fracture of femur following insertion of orthopedic implant, joint

If endorsed: Year of most recent CDP endorsement
2021

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
This measure is currently in use in the HVBP program. The measure has now been updated for this MUC submission: 26 codes were added to the mechanical complications definition. These clinically relevant changes contributed to an increase of ~0.5% (from 2.42% to 2.93%) in the THA/TKA national observed complication rate for 2021 reporting period. We are bringing this updated measure back to the MAP. No other changes to the measure have been made.

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
Year: 2011-2012, 2012-2013

Measure Id: MUC20, MUC523

Workgroups: Hospital, 2012

Programs: Hospital Inpatient Quality Reporting, 2011, Hospital Value Based Purchasing, 2012

Recommendation: February 2012 report, IQR: Support; 2013 report, HVBP: Support

Report Page Number: 2012 report: page 78; 2013 report: page 134

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs
Inpatient Quality Reporting (2015 – scheduled removal 2023 reporting year) Hospital Value Based Purchasing (implemented FY2019 with FY 2021 first reporting year)

What other federal programs are currently using this measure?
Hospital Inpatient Quality Reporting Program; Hospital Value-Based Purchasing Program

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

1. Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for THA/TKA;
2. Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA)

How will this measure be distinguished from other similar and/or competing measures?
No other measure in Hospital IQR or VBP assess complications following primary elective THA/TKA. The measure is complementary to and harmonized with the payment and readmission measures in row 105.

How will this measure add value to the CMS program?
No other measures in Hospital IQR or VBP assess complications following primary elective THA/TKA. The measure is complementary to and harmonized with the payment and readmission measures in row 105. The original version of the measure is currently in use in VBP. Complications are an important outcome for these very common elective procedures.

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If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
See Evidence Attachment

Evidence that the measure can be operationalized
The current version of the measure has already been operationalized. CMS uses the measure in the Hospital VBP program and publicly reports the measure on Care Compare.

The measure was developed using claims data from seven standard analytic files contained in the Chronic Condition Warehouse (CCW) data. The CCW data are derived from the Medicare claims in the Standard Analytic Files. The CCW data contain data from the Medicare FFS institutional and non-institutional claims, enrollment and eligibility information, and assessment data for up to 100% of the Medicare FFS beneficiary population for particular conditions and procedures. The data are organized by predefined chronic conditions, but can also be used to define individualized patient cohorts, as described below. The annual CCW datasets include claims data from all seven standard files (inpatient, skilled nursing facility, outpatient, home health agency, hospice, carrier, and durable medical equipment) that can be linked across care settings, services, supplies, and years using a unique patient identifier. Specific information available in the CCW data includes diagnosis codes, procedure codes, quantity/units of services used, and payments made by CMS, patients, and other insurers to providers.

How is the measure expected to be reported to the program?
Claims

Feasibility of Data Elements
ALL data elements are in defined fields in administrative claims

Evidence of Performance Gap
Variation in complication rates indicates opportunity for improvement. We conducted analyses using data from April 1, 2016 to March 31, 2019 Medicare administrative claims data (n= 962,744 admissions from 3,418 hospitals).

The three-year hospital-level risk standardized complication rate (RSCR) has a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate is 2.4%.

Distribution of Hospital THA/TKA RSCRs over Different Time Periods
Results for each data year

Characteristic//04/2016-03/2017//04/2017-03/2018//04/2018-03/2019//04/2016-03/2019

Number of Hospitals//3274//3271//3250//3418

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Number of Admissions//336445//330765//295534//962744

Mean (SD)//2.6(0.4)//2.4(0.4)//2.3(0.3)//2.5(0.5)

Range (Min-Max)//1.1-9.3//1.3-13//1.2-4.5//1.2-10.6

Minimum//1.1//1.3//1.2//1.2

10th percentile//2.1//2.1//2.0//1.9

20th percentile//2.3//2.2//2.1//2.1

30th percentile//2.4//2.3//2.2//2.3

40th percentile//2.5//2.3//2.2//2.3

50th percentile//2.5//2.4//2.3//2.4

60th percentile//2.5//2.4//2.3//2.5

70th percentile//2.7//2.5//2.4//2.6

80th percentile//2.8//2.7//2.5//2.8

90th percentile//3.0//2.9//2.7//3.0

Maximum//9.3//13.0//4.5//10.6

Unintended Consequences

We did not identify any unintended consequences during measure development and testing. We are committed to monitoring this measure's use and assessing potential unintended consequences over time, such as the inappropriate shifting of care or coding/billing practices, increased patient morbidity and mortality, and other negative unintended consequences for patients.

Outline the clinical guidelines supporting this measure

N/A

Were the guidelines graded?

N/A

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Unable to determine

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Estimate of Annual Improvement in Measure Score
N/A

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure
N/A

Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
During 3 TEP meetings throughout development, including during outcome and cohort development, model building, and risk adjustment methodology

Total Number of Patients and/or Caregivers Consulted
1

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:11

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
1

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Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Working groups; Standard TEP

Total Number of Clinicians/Providers Consulted
16

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
16

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

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Measure Testing Details

Reliability Testing Interpretation of Results

Split sample: Agreement between the two independent assessments of the RSCR for each hospital was 0.524 (moderate reliability)

Signal-to-noise: median 0.87 (ranging from 0.46 to 1.00) which, according to the conventional interpretation, is “almost perfect” (Shrout et al. 1979).

Type of Reliability Testing

Measure Score Reliability

Reliability Testing: Type of Testing Analysis

Signal to Noise; ICC (Intraclass correlation coefficient); Test-Retest

Reliability Testing Sample Size

As noted above, testing was conducted on the currently implemented version of the measure, not the updated version with the addition of 26 complication codes. We present these testing details and results below. The number of measured entities with at least one admission in the cohort was 3,418. The results of the reliability testing was conducted for hospitals with at least 25 cases which included 2,763 hospitals. The 25 cases threshold was used to align with how the measure is publicly reported.

Reliability Testing Statistical Result

Split sample: Agreement between the two independent assessments of the RSCR for each hospital was 0.524 (moderate reliability)

Signal-to-noise: median 0.87 (ranging from 0.46 to 1.00) which, according to the conventional interpretation, is “almost perfect” (Shrout et al. 1979).

References

Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977; 33:159-174.
Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. Psychological Bulletin. 1979; 86:3420-3428.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?

Yes

If yes, specify the number of cases and the percentage of providers

25, 80.8%

Type of Validity Testing

Measure Score Validity

Validity Testing: Type of Validity Testing Analysis

Face Validity

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Validity Testing Sample Size
3418

Validity Testing Statistical Result
We assessed measure score validity by comparing hospitals' overall Star Rating with their RSCRs/ We predicted the THA/TKA complication measure scores would have a small association with the overall hospital star rating scores, with lower RSCRs associated with better Star ratings. Results: The correlation between THA/TKA complications and Star-Rating summary score is -0.185, which suggests that hospitals with lower THA/TKA RSCRs are more likely to have higher Star-Rating summary scores especially at the extremes.

We also assessed validity of the measure by examining the relationship between volume and the measure score for hospitals. We expect scores to be correlated with case volume at the hospital level. Results: There is a general trend that high volume hospitals (those in the upper deciles) have lower RSCRs than hospitals in other volume deciles.

Validity Testing Interpretation of Results
Results demonstrate an observed trend of lower risk-standardized complications with higher star ratings, especially at the extremes, which supports measure score validity. Additionally, this validation approach compared various categories and deciles of hospital THA/TKA admission volume with THA/TKA complication measure scores– these results demonstrate an observed trend of higher hospital volume with lower complication measure scores. Overall, the results above show that the trend and direction of this association is in line with what would be expected.

The TEP also assessed the overall face validity of the measure score as specified. Measure validity is also ensured through the processes employed during development, including regular expert and clinical input, and modeling methodologies with demonstrated validity in claims-based measures.

Measure performance – Type of Score
Ratio

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
Variation in complication rates indicates opportunity for improvement. In 2019 (current version of the measure) we conducted analyses using data from April 1, 2016 to March 31, 2019 Medicare administrative claims data (n= 962,744 admissions from 3,418 hospitals). The three-year hospital-level risk standardized complication rate (RSCR) has a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate is 2.4%.

For the updated version of the measure for this MUC submission, 26 codes were added to the mechanical complications definition. These clinically relevant changes contributed to an increase of ~0.5% (from 2.42% to 2.93%) in the THA/TKA national observed complication rate for 2021 reporting period.

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Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
Centers for Medicare & Medicaid Services

Measure Steward Contact Information
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Long-Term Measure Steward
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N/A

Section 2: Preliminary Analysis – MUC2021-118 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure continues to address a key Healthcare Quality Domain and CMS Meaningful Measure priority area of Safety. This is the only measure within the Hospital IQR Program that evaluates the complication rates following elective THA and/or TKA. A prior version of this measure has been evaluated and supported by the MAP for the Hospital IQR Program in 2011 and was active in the program from 2015-2021, and the measure is currently active in the Hospital Value-Based

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Purchasing (HVBP) Program. The measure has been updated to include 26 codes to the mechanical complication's definition. The developer notes that these clinically relevant changes contributed to an increase of ~0.5 percent (from 2.42 to 2.93 percent) in the THA/TKA national observed complication rate for 2021 reporting period.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is an outcome measure that captures complications of THA and TKA. The developer states that variation in complication rates across hospitals indicates there is room for quality improvement and targeted efforts to reduce these complications can result in better patient care and potential cost savings (Navathe et al, 2017; Cyriac et al., 2016; Borza et al., 2019).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: As of 2010, there were over 370,000 THAs and 600,000 TKAs performed annually. Of these procedures, complications related to anesthesia, comorbidities, and allergic reactions pose a significant quality challenge (Martin et al., 2020; Erens et al., 2021). During a prior NQF endorsement review, the developers provided three-year, hospital-level, risk standardized complication rates (RSCR) from April 1, 2016, to March 31, 2019, using Medicare administrative claims data (n= 962,744 admissions). The RSCRs had a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate was 2.4%. These data demonstrate a range of performance and opportunities for improvement.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital settings. This measure was previously submitted for endorsement review in 2021 and has been updated since the last evaluation. The developer plans to resubmit with updated specifications for endorsement review by the NQF Patient Safety Standing Committee in the Consensus Development Process (CDP). A prior version of this measure has been in use in the Inpatient Quality Reporting (2015 – scheduled removal 2023 reporting year) and the Hospital Value Based Purchasing Program (implemented FY2019 with FY 2021 first reporting year).

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The measure is fully specified and uses administrative claims data and enrollment data and as such, it offers no data collection burden to hospitals or providers. During the prior NQF endorsement review of this measure the Standing Committee had no concerns regarding the feasibility of the measure. The expanded 26 codes for mechanical complication's definition do not pose a feasibility challenge.

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Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital settings. The expanded 26 codes for mechanical complication's definition should be reviewed by the relevant NQF standing committee to confirm validity. The developer clarified for the MAP Hospital the specific 26 codes added. They are specifically: 1) M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate; 2) M96.661 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg; 3) M96.662 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg; 4) M96.669 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg; 5) M96.671 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg; 6) M96.672 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg; 7) M96.679 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg; 8) M97.01XA Periprosthetic fracture around internal prosthetic right hip joint, initial encounter; 9) M97.01XD Periprosthetic fracture around internal prosthetic right hip joint, subsequent encounter; 10) M97.01XS Periprosthetic fracture around internal prosthetic right hip joint, sequela; 11) M97.02XA Periprosthetic fracture around internal prosthetic left hip joint, initial encounter; 12) M97.02XD Periprosthetic fracture around internal prosthetic left hip joint, subsequent encounter; 13) M97.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela; 14) M97.11XA Periprosthetic fracture around internal prosthetic right knee joint, initial encounter; 15) M97.11XD Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter; 16) M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela; 17) M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter; 18) M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter; 19) M97.12XS Periprosthetic fracture; 20) M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela; 21) M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter; 22) M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter; 23) M97.12XS Periprosthetic fracture around internal prosthetic left knee joint, sequela; 24) M97.8XXA Periprosthetic fracture around other internal prosthetic joint, initial encounter; 25) M97.8XXD Periprosthetic fracture around other internal prosthetic joint, subsequent encounter; 26) M97.8XXS Periprosthetic fracture around other internal prosthetic joint, sequela; 27) M97.9XXA Periprosthetic fracture around unspecified internal prosthetic joint, initial encounter; 28) M97.9XXD Periprosthetic fracture around unspecified internal prosthetic joint, subsequent encounter; 29) M97.9XXS Periprosthetic fracture around unspecified internal prosthetic joint, sequela; 30) M96.69 Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate.

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?

Yes/No: No

Justification and Notes: No unintended consequences or implementation challenges have been identified. This measure is currently in use in the Hospital Value-Based Purchasing Program and was previously active in the Hospital Inpatient Quality Reporting Program, but is currently inactive under the

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Hospital IQR Program with an end date of reporting as 1-1-2021 and is scheduled for removal 10-1-2022.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- No issues or concerns

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 votes
2 – 0 votes
3 – 1 votes
4 – 7 votes
5 – 2 votes

MAP Health Equity Advisory Group Input:

The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.1
1 – 0 votes
2 – 4 votes

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3 – 6 votes
4 – 6 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional support for rulemaking

Summary: What is the potential value to the program measure set?

This fully developed and specified measure addresses a critical and preventable safety event in the hospital inpatient setting. The measure is currently in use in the Hospital VBP Program and was previously active in the Hospital IQR Program and has been expanded to include 26 codes to the mechanical complication's definition. The measure is otherwise identical to the previous version of the measure. A MAP Hospital workgroup member noted the importance of communicating the rationale for the updated measure as trending performance across the two measure specifications may be challenging.

Summary: What is the potential impact of this measure on quality of care for patients?

As of 2010, there were over 370,000 THAs and 600,000 TKAs performed annually. Of these procedures, complications for patients related to anesthesia, comorbidities, and allergic reactions pose a significant quality challenge. During NQF endorsement review, the developers provided three-year, hospital-level, risk standardized complication rates (RSCR) from April 1, 2016, to March 31, 2019, using Medicare administrative claims data (n= 962,744 admissions). The RSCRs had a mean of 2.5 percent and range from 1.2-10.6 percent in the study cohort. The median risk-standardized rate was 2.4 percent. These data demonstrate a wide range of performance and opportunities for improvement in patient care. Conditional Support for Rulemaking is recommended pending NQF Standing Committee review of the 26 codes added to the mechanical complication's definition.

Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) appreciates the inclusion of the additional ICD-10 codes for mechanical complications in response to feedback from subject matter experts. While we agree that these changes will likely not significantly impact the reliability and validity of the measure, we encourage the Centers for Medicare and Medicaid Services to update the testing and achieve endorsement of these changes the National Quality Forum before implementation in any quality program. As a result, the FAH requests that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

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American Medical Association

The American Medical Association recommends that the Centers for Medicare and Medicaid Services (CMS) reconsider the addition of the ICD-10 codes for mechanical complications if the National Quality Forum Standing Committee does not agree and continue to monitor whether their addition impacts the reliability and validity of the measure.

Premier, Inc.

Premier conditionally supports adoption of this refined measure. CMS should seek endorsement before moving forward with the measure.

Johnson & Johnson

Johnson & Johnson supports the recommendation of the workgroup to conditionally move forward with support for rulemaking, pending the NQF Standing Committee review of the 26 codes to the mechanical complication's definition. Johnson & Johnson supports meaningful patient-centered care planning measures that promote reductions in treatment-related complications. We further agree with the development of patient-reported outcome performance measures that close gaps in CMS priority measure development areas.

American Hospital Association

The AHA agrees with the MAP's position of Conditional Support, pending the Standing Committee's review of the 26 codes representing complications to be added to the measure's numerator. The previous version of the measure is endorsed and already in use, and has undergone testing for reliability and validity. As long as the measure continues to meet standards for reliability and validity with the inclusion of these new codes, the AHA does not object to its use in the IQR.

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MUC2021-120 Hospital-level, risk-standardized payment associated with an episode of care for primary elective total hip and/or total knee arthroplasty (THA/TKA)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting (IQR) Program

Workgroup
Hospital

Measure Description
This measure estimates hospital-level, risk-standardized payments for an elective primary total THA/TKA episode of care, starting with an inpatient admission to a short-term acute care facility and extending 90 days post admission for Medicare fee-for-service (FFS) patients who are 65 years of age or older.

Numerator
The THA/TKA payment measure assesses risk-standardized payments (RSPs) for Medicare patients for an episode of care that begins with a qualifying elective primary THA/TKA procedure. The measure captures payments for Medicare patients across multiple care settings, services, and supplies (that is, inpatient, outpatient, skilled nursing facility [SNF], home health, hospice, physician/clinical laboratory/ambulance services, durable medical equipment, prosthetics/orthotics, and supplies). Payment adjustments unrelated to clinical care decisions are not considered in the measure outcome. Elective primary THA/TKA procedures are defined as those THA/TKA procedures without any of the following: fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields of the index admission; a concurrent partial hip arthroplasty procedure; a concurrent revision, resurfacing, or implanted device/prosthesis removal procedure; mechanical complication coded in the principal discharge diagnosis field; or, malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field.

Numerator Exceptions
N/A

Denominator
This outcome measure does not have a traditional numerator and denominator. We use this field to define the measure cohort.
The measure cohort includes admissions to non-federal, short-stay, acute-care hospitals for Medicare FFS patients aged 65 years and older with a qualifying THA/TKA procedure, not transferred in from another facility. Patients must also have continuous enrollment in Medicare Part A and Part B benefits for the 12 months prior to the index admission and 90 days post- admission.

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Denominator Exclusions

1) Patients without complete administrative data in the 90 days following the index admission, if alive
2) Patients with no payment information during the index admission 3) Patients discharged against medical advice (AMA)
4) Patients transferred to federal hospitals
5) Patients with more than two THA/TKA procedure codes during the admission
6) Patients transferred into the hospital

Denominator Exceptions

N.A

State of development

Fully Developed

State of Development Details

This measure is fully developed. During initial development, the measure underwent reliability and validity testing at the facility-level. These analyses were conducted on the original version of this measure. The updated measure incorporates 26 mechanical complication ICD-10 codes that were clinically vetted and better reflect the incidence of complications in this cohort that translate to increased payments.

Measure Score Reliability

As a metric of agreement, we calculated the ICC (Landis 1977; Shrout and Fleiss 1979). To calculate the ICC, we used Dataset 2. The agreement between the two independent assessments of each hospital was 0.931, which, according to the conventional interpretation, is “almost perfect” (Shrout et al. 1979).

Facility-level Reliability

The median reliability score of 0.938 calculated with 3 years of data, is considered “almost perfect” (Landis, Koch, 1977).
Measure Score Validity: Validity Indicated by Established Measure Development Guidelines
We developed this measure in consultation with national guidelines for publicly reported outcomes measures, with outside experts, and with the public. The measure is consistent with the technical approach to outcomes measurement set forth in NQF guidance for outcomes measures, CMS Measure Management System (MMS) guidance, and the guidance articulated in the American Heart Association scientific statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes” (Krumholz, Brindis, et al. 2006; NQF 2010).

Data Element Validity: Validity of Claims-Based Measures

Our team has demonstrated for a number of prior measures the validity of claims-based measures for profiling hospitals by comparing either the measure results or individual data elements against medical records. CMS validated the six NQF-endorsed, claim-based measures currently in public reporting (AMI, heart failure, and pneumonia mortality and readmission) with models that used medical record-abstracted data for risk adjustment. Specifically, claims model validation was conducted by building comparable models using abstracted medical record data for risk adjustment for heart failure patients (National Heart Failure data), AMI patients (Cooperative Cardiovascular Project data) and pneumonia

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patients (National Pneumonia Project dataset). When both models were applied to the same patient population, the hospital risk-standardized rates estimated using the claims-based risk-adjustment models had a high level of agreement with the results based on the medical record model, thus supporting the use of the claims-based models for public reporting. Our group has reported these findings in the peer-reviewed literature (Krumholz et al. 2006; Krumholz et al. 2011; Krumholz et al. 2006a; Keenan et al. 2008; Bratzler 2011; Lindenauer 2011).
Validity was also assessed by the TEP. The TEP provided input on the model to strengthen the measure and supported the final measure. The TEP was in agreement with overall face validity of the measure score as specified. Measure validity is also ensured through the processes employed during development, including regular expert and clinical input, and modeling methodologies with demonstrated validity in claims-based measures.

What is the target population of the measure?
The target population includes Medicare fee-for-service (FFS) patients aged 65 years or older undergoing elective THA/TKA.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Orthopedic surgery

Measure Type
Cost/Resource Use

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Claims Data

If applicable, specify the data source
N/A

If EHR 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 one healthcare domain applies to this measure?
Affordability and Efficiency

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
2711

Alternate Measure ID
N/A

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What is the endorsement status of the measure?
Endorsed

NQF ID Number
NQF # 3474

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Other: definition of mechanical complications

If not exactly as endorsed, describe the nature of the differences
The measure was updated to include 26 new codes for mechanical complications:
M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate
M96.661 Fracture of femur following insertion of orthopedic implant, joint

If endorsed: Year of most recent CDP endorsement
2019

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2022

Submitter Comments
This updated measure is fundamentally the same as the previously reviewed and endorsed THA/TKA payment measure. The key change was the addition of 26 new ICD-10 codes related to mechanical complications. These codes were added in response to recommendations made by clinical experts during routine measure maintenance. These additional codes are used in this measure as part of the definition of payments related to THA/THK from day 31-90. The THA/THK payment measure is meant to align with the THA/TKA complications measure to measure value of care. Adding these codes will ensure this alignment.

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
Year: 2013, 2014

Measure ID: MUC59 - X3620 in 2014 and MUC15-295 in 2015

Workgroup: Hospital, 2014 and Hospital, 2015

Programs: Hospital Inpatient Quality Reporting, 2014, Hospital Value Based Purchasing, 2015

Recommendation: 2014, Hospital Inpatient Quality Reporting, Conditional Support; 2015, Hospital Value Based Purchasing, Do Not Support

In 2014, MAP conditionally supported this measure pending a timely review of these measures by the NQF Cost and Resource Use Standing Committee to consider harmonization issues and determine the most parsimonious approach to measuring the costs of hip and knee replacements to minimize the burden and confusion of competing methodologies. MAP noted that joint replacement surgeries are becoming more commonly utilized as Medicare covered 337,419 THA procedures and 750,569 TKA procedures between 2009 and 2012 and annual Medicare payments for THA and TKA exceed $15 billion annually. The group noted that there is significant variation in costs for these procedures that are often related to quality of care as complications and readmissions increase the total payment for post-surgical care. In 2015, MAP did not support this measure because the MAP felt it would overlap with the current Medicare Spending Per Beneficiary Measure and MAP has previously advocated keeping a parsimonious set of measures for the VBP program to avoid rewarding or penalizing a provider multiple times for the same case. MAP noted that post-acute costs could be a driver of variation in this measure.

Report Page Number: Row 197 of the "MAP Final Recommendations CMS 2015" excel spreadsheet for measures considered in 2014 Row 97 of the "MAP Final Recommendations CMS 2016" excel spreadsheet for measures considered in 2015"

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs
Inpatient Quality Reporting (2015 – present)

What other federal programs are currently using this measure?
Hospital Inpatient Quality Reporting Program

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
1. Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for AMI;

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2. Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Heart Failure;
3. Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for Pneumonia;
4. Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA); and
5. Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA).

How will this measure be distinguished from other similar and/or competing measures?
This is a procedure-specific measure that provides payment information for THA/TKA, which is a common procedure.

How will this measure add value to the CMS program?
No other measure in Hospital IQR assesses hospital-level payments following elective THA/TKA procedures.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Due to their frequency and cost, THA and TKA are priority areas for outcome measure development. More than one third of the US population 65 years and older suffers from osteoarthritis [1]. Between 2009 and 2012, there were 337,419 THA procedures and 750,569 TKA procedures for Medicare fee-for-service patients 65 years and older [2]. Estimates place the annual insurer cost of osteoarthritis in the US at $149 billion, with Medicare direct payments to hospitals for THA/TKA exceeding $15 billion annually [3]. Further, there are conflicting data regarding costs after total joint arthroplasty, with evidence to support both increased [4] and decreased costs [5] following arthroplasty, suggesting there is great variation in the costs of a full episode of care for THA and TKA.

The goal of hospital-level resource use measurement is to capture the full spectrum of care in order to incentivize collaboration and shared responsibility for improving patients' health and reducing the burden of their disease. Variation in the cost of a THA or TKA episode of care is often related to the quality of care, where complications and readmissions increase the total payment for post-surgical care. Given the well-documented variation in readmission and complication rates following THA and TKA, there is expected variation in total episode of care costs for the procedures [6]. Birkmeyer et al. found that the average 30-day cost increased by $2,436 among hospitals with the highest quintile of complication rates, compared to the lowest quintile following THA [7]. The same study also found that rehabilitation costs accounted for 50% of "excess" payments among those undergoing THA. Miller et al. found that a major driver of differences in episode payments for THA was that hospitals within Accountable Care Organizations (ACO) had smaller payments for post-discharge care compared to non-ACO hospitals [8]. Taken together, these studies suggest that much of the variation in total episode costs arises in the post-acute setting. Health systems have taken notice of opportunities to improve value by encouraging collaboration of care between hospitals and post-acute providers. [10]. Transparency

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regarding the variation of episode of care payments triggered by THA and TKA helps to guide health systems and providers towards improvement in the value of care.

1. Centers for Disease Control and Prevention (CDC). Osteoarthritis. 2011; http://www.cdc.gov/arthritis/basics/osteoarthritis.htm. Accessed August 13, 2013.
2. Suter LG, Grady JN, Lin Z, et al. 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). March 2013.
3. Miller DC, Gust C, Dimick JB, Birkmeyer N, Skinner J, Birkmeyer JD. Large variations in Medicare payments for surgery highlight savings potential from bundled payment programs. Health affairs (Project Hope). Nov 2011;30(11):2107-2115.
4. Bozic KJ, Stacey B, Berger A, Sadosky A, Oster G. Resource utilization and costs before and after total joint arthroplasty. BMC health services research. 2012;12:73.
5. Hawker GA, Badley EM, Croxford R, et al. A population-based nested case-control study of the costs of hip and knee replacement surgery. Med Care. 2009;47(7):732-741.
6. Suter LG, et al., Medicare Hospital Quality Chartbook 2013: Performance Report on Outcome Measures, 2013.
7. Birkmeyer JD, Gust C, Dimick JB, Birkmeyer NJ, Skinner JS. Hospital quality and the cost of inpatient surgery in the United States. Annals of surgery. 2012;255(1):1-5.
8. Miller DC, Ye Z, Gust C, Birkmeyer JD. Anticipating the effects of accountable care organizations for inpatient surgery. JAMA surgery. Jun 2013;148(6):549-554.
9. CMS. Bundled Payments for Care Improvement (BPCI) Initiative: General Information. http:/ / innovation.cms.gov/initiatives/bundled-payments/ [accessed Jan 7, 2014]
10. Miller DC, Ye Z, Gust C, Birkmeyer JD. Anticipating the effects of accountable care organizations for inpatient surgery. JAMA surgery. Jun 2013;148(6):549-554.

Evidence that the measure can be operationalized

The data sources for this measure include Medicare administrative claims and enrollment information for patients with hospitalizations for a THA/TKA in a given three-year period. The period for public reporting of the THA/TKA measure aligns with the 90-day THA/TKA complication measure. Medicare administrative claims for the 12 months prior to and during the index admission are used for risk adjustment.

The datasets also contain price-standardized payments for Medicare patients across all Medicare settings, services, and supplies (that is, inpatient, outpatient, SNF, home health agency, hospice, physician/clinical laboratory/ambulance services, and durable medical equipment, prosthetics/orthotics, and supplies). The CMS Standardization Methodology for Allowed Amount is applied to the claims to calculate the measures.

How is the measure expected to be reported to the program?

Claims

Feasibility of Data Elements

ALL data elements are in defined fields in administrative claims

Evidence of Performance Gap

Consistent with the other publicly reported measures, we calculate interval estimates for the risk-standardized payment to characterize the amount of uncertainty associated with the payment, compare

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the interval estimate to the average national payment, and categorizes hospitals as “higher than,” “less than,” or “no different than” the average national payment (Kim et al. 2014). After adjusting for patient case mix, the RSP at the hospital level has a median (interquartile range) of $22,408 ($20,847, $24,174). The mean ± SD risk-standardized hospital payment is $23,686 ± $2,655, ranging from $15,481 to $49,496 across 3,452 hospitals. The variation in rates suggests that there are meaningful differences across hospitals in risk standardized payments associated with a 90 day episode of care for patients undergoing elective primary THA/TKA.

Reference

Kim N, Ott L, Lin Z, Zhou S, Keshawarz A, Spivack S, Xu X, George E, Parisi M, Reilly E, Zribi R, Suter L, Krumholz HM. Hospital-Level, Risk-Standardized Payment Associated with a 90-Day Episode of Care for Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Version 1.0) 2014 Measure Methodology Report. December 2014; Centers for Medicare & Medicaid Services (CMS). Available at: http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid

Unintended Consequences

We did not identify any unintended consequences during measure development, testing or in the implementation of the existing measure. We are committed to monitoring this measure’s use and assessing potential unintended consequences over time, such as the inappropriate shifting of care or coding/billing practices, increased patient morbidity and mortality, and other negative unintended consequences for patients.

Outline the clinical guidelines supporting this measure

This measure, which uses standardized payments, reflects differences in the management of care for patients who undergo an elective THA/TKA, both during hospitalization and immediately post-discharge. By focusing on these common procedures, value assessments may provide actionable feedback to hospitals and incentivize targeted improvements in care.
Also, this measure is intended to be paired with other quality measures, such as risk-standardized mortality. As such the goal is to incentivize improvements in quality that will lead to better outcomes at lower costs of care.

Were the guidelines graded?

N/A

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Unable to determine

Estimate of Annual Improvement in Measure Score

N/A

Type of Evidence to Support the Measure

Empirical data

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Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
The TEP met three times. TEP members provided input on the measure cohort definition, payment methodology, outcome window, risk adjustment, and disparities analyses.

Total Number of Patients and/or Caregivers Consulted
1

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:14

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
1

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

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Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP; Other: Clinical Experts

Total Number of Clinicians/Providers Consulted
15

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
13

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
The Intraclass Correlation Coefficient (ICC) score demonstrates strong agreement across samples, indicating that the measure score is reliable.

Type of Reliability Testing
Measure Score Reliability; Data Element Reliability

Reliability Testing: Type of Testing Analysis
Intraclass correlation coefficient (ICC); Test-Retest

Reliability Testing Sample Size
3452

Reliability Testing Statistical Result
Reliability testing was conducted on the original version of this measure. As a metric of agreement we calculated the ICC (Landis 1977; Shrout and Fleiss 1979). The agreement between the two independent

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assessments of each hospital was 0.955931, which, according to the conventional interpretation, is "almost perfect" (Shrout et al. 1979).

References

Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977; 33:159-174.
Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. Psychological Bulletin. 1979; 86:3420-3428.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?

Yes

If yes, specify the number of cases and the percentage of providers

The minimum number of denominator cases per measured entity for public reporting is 25. In the test sample, 2,791 (80.18%) facilities met the minimum requirement.

Type of Validity Testing

Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis

Face Validity

Validity Testing Sample Size

2614

Validity Testing Statistical Result

Measure score validity was conducted on the original version of this measure and is demonstrated through prior validity testing done on our other claims-based measures, through use of established measure development guidelines, and by systematic assessment of measure face validity by a Technical Expert Panel (TEP) of national experts and stakeholder organizations. Additionally, we have performed prior validity testing on our other claims-based measures, and applied established measure development guidelines. Furthermore, the addition of new ICD-10 codes to identify complications of care was vetted by a number of clinicians in the field of orthopedics.

Validity Testing Interpretation of Results

These results demonstrate TEP agreement with overall face validity of the measure score as specified. Measure validity is also ensured through the processes employed during development, including regular expert and clinical input, and modeling methodologies with demonstrated validity in claims-based measures.

Measure performance – Type of Score

Continuous Variable

Measure Performance Score Interpretation

Other: Results of the measure alone do not necessarily reflect the quality of care provided by hospitals but simply whether the total episode payments are greater than or less than would be expected for an average hospital with a similar case mix.

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Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

Of 3,481 hospitals in the study cohort, 733 (21.06%) had a payment "Greater than the National Payment," 1,087 (32.23%) had a payment "No Different than the National Payment," and 971 (27.89) had a payment "Less than the National Payment." 690 (19.82%) were classified as "Number of Cases Too Small" (fewer than 25) to reliably estimate the hospital's RSP.

Benchmark, if applicable

Comparative estimates are provided by classifying hospitals as less than average, no different than average, or greater than average payment depending on the span of their confidence interval in comparison with the national average payment amount (i.e., the benchmark). To categorize hospital payments, we estimate each hospital's RSP and the corresponding 95% interval estimate. As with all estimates, there is a degree of uncertainty associated with the RSP. The interval estimate is a range of probable values around the RSP that characterizes the amount of uncertainty associated with the estimate. A 95% interval estimate indicates that there is 95% probability that the true value of the RSP lies between the lower limit and the upper limit of the interval. In an effort to provide fair comparisons, we provide three categories (less than, no different than, or greater than the national average payment amount), which allows for conservative discrimination of hospital RSPs.

Measure Contact Information

Measure Steward

Centers for Medicare and Medicaid Services

Measure Steward Contact Information

James Poyer
200 Independence Ave
Washington, DC 20001
James.Poyer@cms.hhs.gov
Phone Number: 410-786-2261

Long-Term Measure Steward

N/A

Long-Term Measure Steward Contact Information

N/A

Primary Submitter Contact Information

Samantha Mancuso
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Section 2: Preliminary Analysis – MUC2021-120 Hospital-level, risk-standardized payment associated with an episode of care for primary elective total hip and/or total knee arthroplasty (THA/TKA)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: This measure addresses the Hospital IQR Program high-priority area of care coordination and a CMS Meaningful Measures 2.0 priority area of affordability and efficiency. There are no other measures in the Hospital IQR program assessing standardized payment for Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). A prior version of this measure has been evaluated and supported by the MAP for the Hospital IQR Program and is currently active in the program.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: This measure was designed to be used with harmonized complications and readmissions measures and aspires to drive quality improvement in care coordination and post-acute costs and resource use. Following surgery, some patients may require rehabilitation stays in inpatient or nursing facilities, follow-up visits, physical therapy, or pain management. (Martin et al., 2021; Erens et al., 2021). Complications for these surgeries may be preventable with appropriate surgical technique and sufficient postoperative management (Martin et al., 2020), indicating that higher quality care may play a role in cost variation. The NQF Cost and Efficiency Standing Committee reviewed a prior version of this measure in 2018 and expressed concerns with using the cost measure as a proxy for complications, but ultimately passed the measure on validity and overall scientific acceptability based on evidence provided by the developer.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: As of 2010, there were over 370,000 THAs and 600,000 TKAs performed annually. Of these procedures, complications related to anesthesia, comorbidities, and allergic reactions pose a significant quality challenge (Martin et al., 2021; Erens et al., 2021). The developer cites evidence that the risk-standardized payment at the hospital level has a median (interquartile range) of $22,408 and the mean ± SD risk-standardized hospital payment is $23,686 ± $2,655, ranging from $15,481 to $49,496 across 3,452 hospitals (Kim et al., 2014). This variation demonstrates a range of performance and opportunities for improvement.

During 2018 endorsement review, NQF Standing Committee members expressed concern that while the data demonstrated variation in payments, it was unclear whether this indicated disparities in care or the influence of social factors. Ultimately the Committee agreed the developer presented sufficient evidence of variation and that the measure was of high importance.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: There are no other measures in the Hospital IQR program assessing payment for Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA), however, the measure is

consistent in nature with three other measures assess standardized payment for acute myocardial infarction, pneumonia, and heart failure.
The measure is harmonized with two other measures: Hospital-Level 30-Day, All-Cause Risk Standardization Readmission Rate (RSRR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Hospitalization (Hospital IQR program, inactive; Hospital Readmission Reduction Program, active) and Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (Hospital IQR program, inactive; Hospital Value-Based Purchasing Program, active.) The NQF Standing Committee noted during the 2018 endorsement review that these procedures are increasingly moving to the outpatient setting (Martin et al., 2021; Erens et al., 2021), which could create opportunities for the measure to be applied to additional outpatient care setting quality reporting programs pending appropriate testing.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified and uses administrative claims data and enrollment data and as such, it offers no data collection burden to hospitals or providers. During the prior NQF endorsement review of this measure the Standing Committee had no concerns regarding the feasibility of the measure. The expanded 26 codes for mechanical complication's definition do not pose a feasibility challenge.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital settings. The expanded 26 ICD-10 codes for mechanical complication's definition should be reviewed by the relevant NQF Standing Committee to confirm validity. The developer clarified for the MAP Hospital the specific 26 codes added. They are specifically: 1) M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate; 2) M96.661 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg; 3) M96.662 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg; 4) M96.669 Fracture of femur following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg; 5) M96.671 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, right leg; 6) M96.672 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, left leg; 7) M96.679 Fracture of tibia or fibula following insertion of orthopedic implant, joint prosthesis, or bone plate, unspecified leg; 8) M97.01XA Periprosthetic fracture around internal prosthetic right hip joint, initial encounter; 9) M97.01XD Periprosthetic fracture around internal prosthetic right hip joint, subsequent encounter; 10) M97.01XS Periprosthetic fracture around internal prosthetic right hip joint, sequela; 11) M97.02XA Periprosthetic fracture around internal prosthetic left hip joint, initial encounter; 12) M97.02XD Periprosthetic fracture around internal prosthetic left hip joint, subsequent encounter; 13) M97.02XS Periprosthetic fracture around internal prosthetic left hip joint, sequela; 14) M97.11XA Periprosthetic fracture around internal prosthetic right knee joint, initial encounter; 15) M97.11XD Periprosthetic fracture around internal prosthetic right knee joint, subsequent encounter; 16) M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela; 17) M97.12XA Periprosthetic fracture around internal prosthetic left knee joint, initial encounter; 18) M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter; 19) M97.12XS Periprosthetic fracture; 20) M97.11XS Periprosthetic fracture around internal prosthetic right knee joint, sequela; 21) M97.12XA Periprosthetic fracture around internal prosthetic left

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knee joint, initial encounter; 22) M97.12XD Periprosthetic fracture around internal prosthetic left knee joint, subsequent encounter; 23) M97.12XS Periprosthetic fracture around internal prosthetic left knee joint, sequela; 24) M97.8XXA Periprosthetic fracture around other internal prosthetic joint, initial encounter; 25) M97.8XXD Periprosthetic fracture around other internal prosthetic joint, subsequent encounter; 26) M97.8XXS Periprosthetic fracture around other internal prosthetic joint, sequela; 27) M97.9XXA Periprosthetic fracture around unspecified internal prosthetic joint, initial encounter; 28) M97.9XXD Periprosthetic fracture around unspecified internal prosthetic joint, subsequent encounter; 29) M97.9XXS Periprosthetic fracture around unspecified internal prosthetic joint, sequela; 30) M96.69 Fracture of other bone following insertion of orthopedic implant, joint prosthesis, or bone plate.

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?
Yes/No: No
Justification and Notes: The measure developer states that there have currently been no unintended consequences identified from the measure's implementation in the Hospital IQR Program. No concerns were raised in public comment during the measure's initial endorsement review.

PAC/LTC Core Concept?
Yes/No: N/A
Justification: N/A

Impact Act Domain
Yes/No: N/A
Justification: N/A

Hospice High Priority Areas
Yes/No: N/A
Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- Concern about rural patients being excluded due to transfers from rural health facilities

Data collection issues:

- None

Calculation issues:

- Concern with low-case volume. The minimum number of cases is 25; but in some rural settings the number of these procedures may not meet the minimum case volume.

Unintended consequences:

- There was some concern on whether this measure takes into account that more acute patients, as these patients transferred out of critical access hospitals in rural settings

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.9
1 – 0 votes
2 – 1 votes

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3 – 2 votes
4 – 10 votes
5 – 3 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- Concern whether variation in payment is influenced by disparities in care
- This is a dynamic area, in moving from inpatient to outpatient, and those in the outpatient settings are usually younger people, and this measure should monitor equity over time
- There are access concerns here as well; this measure is complex and complicated and stratifying would add little value
- There is concern about the pairing of this cost measure to a quality measure. This measure alone may not adequately reflect the care received as some patients may not have access to these treatments

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 2.5
1 – 0 votes
2 – 11 votes
3 – 7 votes
4 – 1 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional support for rulemaking, pending NQF Standing Committee review of the 26 codes added to the mechanical complication's definition.

Summary: What is the potential value to the program measure set?

This fully developed and tested measure addresses risk-standardized payment for elective THA and TKA. The developer cites evidence that the risk-standardized payment at the hospital level has a median of $22,408, and the mean ± SD risk-standardized hospital payment is $23,686 ± $2,655. This variation demonstrates a range of performance and opportunities for improvement. No other measure in the Hospital IQR Program addresses payment for elective THA and TKA.

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Summary: What is the potential impact of this measure on quality of care for patients?
As of 2010, there were over 370,000 THAs and 600,000 TKAs performed annually. This recently updated measure was designed to be used with harmonized complications and readmissions measures and aspires to drive quality improvement in care coordination and post-acute costs and resource use. A previous version of the measure has been active in the Hospital IQR Program since 2018. Conditional support for rulemaking is recommended, pending NQF Standing Committee review of the 26 codes added to the mechanical complication's definition.

Section 3: Public Comments

Federation of American Hospitals
The Federation of American Hospitals (FAH) appreciates the inclusion of the additional ICD-10 codes for mechanical complications in response to feedback from subject matter experts. While we agree that these changes will likely not significantly impact the reliability and validity of the measure, we encourage the Centers for Medicare and Medicaid Services to update the testing and achieve endorsement of these changes the National Quality Forum before implementation in any quality program. As a result, the FAH requests that the highest level of MAP recommendation be “Conditional Support for Rulemaking.”

American Medical Association
The American Medical Association recommends that the Centers for Medicare and Medicaid Services (CMS) reconsider the addition of the ICD-10 codes for mechanical complications if the National Quality Forum Standing Committee does not agree and continue to monitor whether their addition impacts the reliability and validity of the measure.

Premier, Inc.
Premier conditionally supports adoption of this refined measure. CMS should seek endorsement before moving forward with the measure.

Johnson & Johnson
Johnson & Johnson supports the recommendation of the workgroup to conditionally move forward with support for rulemaking, pending the NQF Standing Committee review of the 26 codes to the mechanical complication's definition. Johnson & Johnson recognizes the importance of managing episode costs associated with THA/TKA surgical episodes and encourages NQF to consider the use of episode cost measures in combination with measures that further recognize total cost of care that a provider delivers, where savings achieved from appropriate medication use are recognized.

American Hospital Association
The AHA agrees with the MAP’s position of Conditional Support, pending the Standing Committee’s review of the 26 codes representing complications to be added to the measure’s numerator. The previous version of the measure is endorsed and already in use, and has undergone testing for reliability and validity. As long as the measure continues to meet standards for reliability and validity with the inclusion of these new codes, the AHA does not object to its use in the IQR.

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MUC2021-131 Medicare Spending Per Beneficiary (MSPB) Hospital

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting Program, Hospital Value-Based Purchasing Program

Workgroup
Hospital

Measure Description
The measure evaluates hospitals' efficiency relative to the efficiency of the national median hospital and assesses the cost to Medicare for Part A and Part B services performed by hospitals and other healthcare providers during an MSPB Hospital episode, which is comprised of the periods 3-days prior to, during, and 30-days following a patient's hospital stay. The measure is not condition specific and uses standardized prices when measuring costs. Eligible beneficiary populations include beneficiaries enrolled in Medicare Parts A and B who were discharged between January 1 and December 1 in a calendar year from short-term acute hospitals paid under the Inpatient Prospective Payment System.

Numerator
The numerator of the MSPB Hospital measure is the hospital's average risk-adjusted episode cost, also referred to as the MSPB Amount. The MSPB Amount is calculated as the average ratio of Medicare Part A and Part B standardized episode costs to predicted episode costs from all episodes at the hospital, multiplied by the average standardized episode cost nationwide.

Numerator Exceptions
The following episode-level exclusions apply to all episodes triggered at a particular hospital:

1. The beneficiary has a primary payer other than Medicare for any time during the episode window or 90-day lookback period prior to the episode start day
2. The beneficiary was not enrolled in Medicare Parts A and B for the entirety of the lookback period plus episode window, or was enrolled in Part C for any part of the lookback plus episode window
3. The beneficiary's date of birth is missing
4. The beneficiary's death date occurred before the episode ended
5. The index admission for the episode did not occur in a subsection (d) hospital paid under the IPPS or occurred in an acute hospital in Maryland
6. The discharge of the inpatient stay occurred in the last 30 days of the
7. measurement period
8. The index admission for the episode was involved in an acute-to-acute hospital transfer
9. The inpatient claim of the inpatient stay indicated a $0 actual payment or a $0 standardized payment.

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Denominator
The denominator of the MSPB Hospital measure is the episode-weighted median MSPB Amount across all episodes nationally.

Denominator Exclusions
The following episode-level exclusions apply to episodes triggered at all eligible hospitals in the nation:
(a) The beneficiary has a primary payer other than Medicare for any time during the episode window or 90-day lookback period prior to the episode start day
(b) The beneficiary was not enrolled in Medicare Parts A and B for the entirety of the lookback period plus episode window, or was enrolled in Part C for any part of the lookback plus episode window
(c) The beneficiary's date of birth is missing
(d) The beneficiary's death date occurred before the episode ended
(e) The index admission for the episode did not occur in a subsection (d) hospital paid under the IPPS or occurred in an acute hospital in Maryland
(f) The discharge of the inpatient stay occurred in the last 30 days of the measurement period
(g) The index admission for the episode was involved in an acute-to-acute hospital transfer
(h) The inpatient claim of the inpatient stay indicated a $0 actual payment or a $0 standardized payment.

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
The measure underwent extensive testing prior to the NQF endorsement submission in August, 2020. Specifically, the following testing was conducted: reliability, validity, exclusions, evidence-based risk-adjustment strategy, performance gap, and missing data. For reliability and validity testing results, please refer to the "Reliability Testing" and "Validity Testing" subsections of this form.

What is the target population of the measure?
Medicare Fee for Service

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Other: N/A

Measure Type
Efficiency

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Claims Data

If applicable, specify the data source
N/A

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If EHR 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 one healthcare domain applies to this measure?
Affordability and Efficiency

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
2751

Alternate Measure ID
MSPB 1

What is the endorsement status of the measure?
Endorsed

NQF ID Number
NQF # 2158

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Target Population; Other: See next field

If not exactly as endorsed, describe the nature of the differences
The current version of the MSPB Hospital measure is NQF endorsed (NQF ID #2158). The revised version of the measure is currently undergoing NQF endorsement, and is expected to receive its endorsement status in the summer of 2021.

Refinement 1: In the current MSPB Hospital measure, inpatient readmissions occurring in the 30-day post-discharge period of an episode cannot initiate (or trigger) a new episode. The methodology was refined to allow readmissions to trigger a new episode and include an indicator variable in the risk adjustment model to account for the differences in expected costs for episodes that are readmissions. Allowing readmissions to trigger new episodes (i) increases the number of episodes for which a provider can be scored and aligns the incentives of the cost measure during readmissions; and (ii) captures potentially high-cost services that are otherwise excluded. By allowing readmission inpatient stays to trigger new episodes in the MSPB Hospital measure, the number of episodes used in MSPB Hospital measure score calculations increased by 16.97 percent from 5.10 million to 5.97 million episodes. Further, the inclusion of an indicator variable to control for the readmission characteristic of an episode controlled for the higher observed cost of readmission-based episodes (mean: $26,552) relative to non-readmission episodes (mean: $21,565), as evidenced by average observed to expected episode cost ratios that are close to 1.00 and by differences between these average observed to expected episode cost ratios for readmission and non-readmission episode types that were largely less than 1 percent.

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Taken with the change in measure risk adjustment calculation that ensures equal weight of each risk-adjusted episode at a hospital, the MSPB Hospital measure refinements resulted in score changes of less than 3 percent, relative to the original measure methodology, for approximately 94.5 percent of providers. Refinement 2: One step of the current MSPB Hospital methodology calculates the measure score as the sum of total observed costs divided by the sum of total expected costs across all episodes attributed to a hospital. The refinement of this step changes the calculation to the average episode's ratio of observed costs divided by expected costs across the population of attributed episodes for a hospital. Specifically: • Current methodology to calculate the MSPB Amount: ((Sum of Observed Costs//# of Attributed Episodes) / (Sum of Expected Costs/# of Attributed Episodes)) * Average Observed Cost Nationally • Revised methodology to calculated the MSPB Amount: (Sum (Observed Costs/Expected Costs) / /# of Attributed Episodes) * Average Observed Cost Nationally Changing the measure calculation (i) slightly increases measure reliability with minimal score changes; and (ii) evenly weights attributed episodes in the final performance score, where previously good or poor performance on more expensive episodes could have more weight in the final provider's score. The overall impact of this refinement on measure scores was generally limited (e.g., less than 3 percent change in the overall score distribution end points), while allowing each risk-adjusted episode equal weight in a provider's measure score.

If endorsed: Year of most recent CDP endorsement
2017

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
None

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
2011, 2012
2011: MUC41 , 2012: 1643
MAP Hospital Workgroup
2012 MAP: HVBP and HIQR
2013 MAP: HVBP and HIQR
Recommendation: 2012 MAP: Hospital VBP and Hospital IQR
MAP's recommendation: Support
2013 MAP: Hospital VBP and Hospital IQR;
MAP's recommendation: Support
Input on Measures Under Consideration by HHS for 2012 Rulemaking, Final Report (February, 2012): MAP reviewed the MSPB Hospital measure for the following programs: Hospital IQR; Hospital VBP; Long-Term Care Hospital Quality Reporting (LTCHQR); and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR)
MAP recommendations: "Though measures of cost have been identified as a high-priority gap area, MAP could not support the inclusion of the Medicare Spending per Beneficiary measure at this time. However, MAP strongly supports the direction of this measure pending additional specification and testing. MAP encourages harmonization with the similar measure concept under consideration within the Physician Value-Based Payment Modifier program."

Support Direction. Support measure concept but need specifications."
Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report (February, 2013): MAP reviewed the MSPB Hospital measure for the following programs: Hospital IQR, Value-Based Payment Modifier Program, and Hospital VBP.
MAP Recommendations: "MAP supported the Medicare Spending per Beneficiary measure, noting the statutory requirement for this measure and that this measure is expected to be submitted for NQF-endorsement this year", and "Support: Addresses specific program attributes. Addresses an NQS priority not adequately addressed in the program measure set".
Input on Measures Under Consideration by HHS for 2012 Rulemaking, Final Report (February, 2012): Pages 83 and 84
MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report (February, 2013): Pages 30 and 136.

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs
Hospital Value-Based Purchasing (FY2015 – present), Hospital Inpatient Quality Reporting (FY2014 – FY2019).

What other federal programs are currently using this measure?
Hospital Value-Based Purchasing Program

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Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
Sec. 1886 (o) (2) (B) (ii) of the Social Security Act.

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
In the United States, healthcare costs consume an ever-increasing amount of our nation's resources. One source of these rising healthcare costs is payment systems that reward medical inputs rather than outcomes. Medicare is transforming from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation. To advance this transformation, the Centers for Medicare & Medicaid Services (CMS) provides financial incentives to hospitals based on their performance on selected quality measures. These measures include evaluations of hospitals' clinical process of care, patient perspective of care, outcomes, and efficiency. By measuring Medicare spending through the MSPB Hospital measure, CMS aims to reward hospitals that can provide efficient care at a lower cost to Medicare.

The MSPB Hospital measure evaluates hospitals' risk-adjusted episode costs relative to the risk-adjusted episode costs of the national median hospital. This scoring allows hospitals to improve their score by spending less than the episode-weighted risk-adjusted median cost during a given performance period through improved care coordination and provision of efficient care. For instance, hospitals can decrease (i.e., improve) their risk-adjusted episode costs through actions such as: 1) improving coordination with post-acute providers to reduce the likelihood post-discharge of adverse events, 2) identifying unnecessary or low-value post-acute services and reducing or eliminating these services, or 3) shifting post-acute care from more expensive services (e.g., skilled nursing facilities) to less expensive services (e.g., home health) in cases that would not affect patient outcomes. Care coordination helps ensure a patient's needs and preferences for care are understood, and that those needs and references are shared between providers, patients, and families as a patient moves from one healthcare setting to another. People with chronic conditions, such as diabetes and hypertension, often receive care in multiple settings from numerous providers. As a result, care coordination among different providers is required to avoid waste, over-, under-, or misuse of prescribed medications and conflicting plans of care.

Evidence that the measure can be operationalized
This is a claims-based measure and will not require any additional submission of data.

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How is the measure expected to be reported to the program?
Claims

Feasibility of Data Elements
ALL data elements are in defined fields in administrative claims

Evidence of Performance Gap
Analysis of all IPPS eligible hospitals with at least 25 episodes for the 2018 performance period shows a large range of provider scores on the MSPB Hospital measure. The MSPB Hospital measure score has the following distributional characteristics:

- Mean: 0.99, standard deviation: 0.08
- Median: 0.99
- Min: 0.49, max: 1.68
- Interquartile range spans from 0.94 to 1.03

The score decile distribution for the 2018 performance period is:

- 10th: 0.90
- 20th: 0.93
- 30th: 0.95
- 40th: 0.97
- 50th: 0.99
- 60th: 1.01
- 70th: 1.02
- 80th: 1.05
- 90th: 1.08

Analysis of MSPB Hospital measure score changes between 2017 and 2018 showed that hospital scores do vary over time, as 48.8 percent of providers evidenced improved (lower) scores. The distribution in score change between these two years, with negative values indicating improvement, is as follows:

- Min: -166.24%
- 5th: -17.54%
- 10th: -4.15%
- 25th: -1.76%
- 50th: 0.10%
- 75th: 2.01%
- 90th: 4.41%
- 95th: 18.92%
- Max: 35.68%

Unintended Consequences
No unintended consequences to individuals or populations have been identified during testing, and no evidence of unintended negative consequences to individuals or populations have been reported since implementation.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

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If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
3,218 acute care hospital providers

Estimate of Annual Improvement in Measure Score
N/A

Type of Evidence to Support the Measure
Systematic Review; Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted; Stratified

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
The patients/caregivers that were part of the standard Technical Expert Panel (TEP) were engaged once, at the onset of the re-evaluation process for the measure.

Total Number of Patients and/or Caregivers Consulted
2

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
2:18

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2

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Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
18

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
18

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
The correlation coefficients for scores across the 2018 and 2017 performance periods were lower than scores compared across the randomly split 2018 performance period sample. This difference is expected as the two-year sample may capture additional variation in hospital performance across performance periods. The Shrout-Fleiss intraclass correlation coefficients were similar to the Pearson correlation

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coefficients at 0.83 and 0.79 for the 2018 split-sample and 2017 and 2018 sample. As ICC(2,1) imposes a common variance for provider across samples, its use is most appropriate in assessing the reliability of the 2018 performance period random split-sample.
Overall, the reliability of the MSPB Hospital measure is high, including when its current 25-episode minimum is applied to balance measure reliability and inclusiveness. The MSPB Hospital measure performance period episode minimum is 25 for the HVBP program, and the signal-to-noise analysis indicates that this episode minimum maintains the measure's high reliability.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise; ICC (Intraclass correlation coefficient)

Reliability Testing Sample Size
3,148 hospitals

Reliability Testing Statistical Result
Reliability Score Results: The signal-to-noise analysis sought to determine the extent to which variation in the measure is due to true, underlying provider performance, rather than variation within provider, from provider episodes. The closer a reliability score is to 1.0, the larger the between-group variance is relative to the within-group variance, the greater the suggestion that the measure is capturing the systematic differences between hospitals. The average reliability score of hospitals with at least 25 episodes was 0.92. The median reliability score for hospitals with at least 25 episodes was 0.96 and the reliability score interquartile range spanned from 0.91 to 0.98. While higher episode-minima yield higher reliability results, the application of higher episode-minimums reduces the number of providers receiving a measure score. Additionally, 99.0 percent of providers met or exceeded a 0.4 reliability score, a standard generally considered as the threshold for 'moderate' reliability, and 94.3 percent of providers met or exceeded a 0.7 reliability score.

Split-sample Reliability Testing Results: The multi-sample testing examined agreement between two hospital measure scores from (1) a randomly split set of episodes in the 2018 performance period and (2) the 2018 and 2017 performance periods. We analyzed score agreement from Pearson and Shrout-Fleiss intraclass correlation coefficients ICC(2,1). Coefficients close to 1.0 indicate high agreement in scoring between samples and suggest that performance scores are identified more by provider characteristics, like efficiency of care, than by random variation. The Pearson correlation coefficient was 0.83 for the 2018 split-sample and 0.79 for the 2017 and 2018 sample. The Shrout-Fleiss intraclass correlation coefficients were similar at 0.83 and 0.79 for the 2018 split-sample and 2017 and 2018 sample, respectively.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
A case minimum of 25 episodes per hospital was applied for the reliability testing.98 percent of hospitals met the minimum denominator requirement. Specifically, there were 3,218 acute care hospital providers with an MSPB Hospital measure score in 2018. For the reliability testing, the sample was restricted to 3,148 providers who met the 25 episode case minimum that is currently imposed on the MSPB Hospital measure under the Hospital VBP program.

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Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Correlation; Face Validity

Validity Testing Sample Size
5,965,189 episodes (from 3,148 hospitals that met the 25-episode case minimum)

Validity Testing Statistical Result
Face Validity: The potential measure refinements were tested by the measure developer and reviewed by a technical expert panel in February 2020 as part of the MSPB Hospital measure's re-evaluation. The TEP comprised 20 members with expertise in cost measure development and evaluation and quality improvement from diverse backgrounds, including clinicians, healthcare providers, academia, and patient advocacy organizations. Though no official vote was taken, panelists agreed that maintaining MSPB Hospital measure's holistic "all-cost" approach, allowing readmissions to trigger new MSPB Hospital episodes to increase measure surveillance, and updating the MSPB Hospital measure's MSPB Amount (score numerator) calculation to evenly weight all of a hospital's episodes were appropriate refinements. Panelists further provided additional considerations for ongoing social risk factor testing, like examining the impact of controlling for the Area Deprivation Index.

Observed to Expected Cost Ratios: For this analysis, the relationship between risk-adjusted episode cost ratios and episodes with and without post-admission events that are known indicators of high cost or intensive care was examined. Specifically, the developer examined the observed to expected cost (O/E) ratios of episodes with acute care readmissions, episodes with any post-acute care (PAC) facility use, and episodes with PAC skilled nursing facility (SNF) use. The developer examined episodes with PAC-SNF use separately as such use has traditionally accounted for the largest share of Medicare's fee-for-service PAC expenditures. The mean, standard deviation, and percentile distribution of observed to expected (O/E) episode cost ratios for episodes with high-cost post-admission events, such as readmissions or post-acute care, were higher than their counter parts. For example, episodes with an acute care re-hospitalization an average O/E ratio of 1.55 and an interquartile range of 1.07 to 1.85, while episodes without such readmissions had an average O/E ratio of 0.89 and an interquartile range of 0.60 to 1.02. Service Utilization: For this analysis, the relationship between a hospital's average expected episode cost (the average "E" in O/E cost ratios) and average episode rates of several service use categories was examined. Per episode service use, particularly for higher cost events or events that require further care, like surgical procedures, may be positively correlated with expected episode costs if the regression model that the MSPB Hospital measure uses for risk adjustment predicts patient need for such services well. Most service use/setting categories were moderately and positively correlated to the average predicted episode cost, with the correlations across all services categories average +0.487 and procedure use evidencing the strongest correlation (+0.721).

Correlations with Other Measures: For this analysis, the relationship between the MSPB Hospital measure and other cost-specific measures, efficiency-related measures, and measures in other HVBP program domains was examined. Specifically, the analysis compared MSPB Hospital measure components that may more closely relate to other measure scores and rates. For example, it compared the average expected episode amount to other measure performance period rates, for measures that had a literature-based or hypothesized conceptual relationship to the MSPB Hospital measure. All three Payment & Value of Care measures, capturing 30-day Medicare payments for acute myocardial infarction, heart failure, and pneumonia conditions, were positively and weakly (or moderately)

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correlated with the hospital average predicted episode cost. All four Timely & Effective Care measures, capturing time spent in the ED before being sent home or admitted, were also positively and weakly or moderately correlated with average predicted episode costs.

Validity Testing Interpretation of Results

Observed to Expected Cost Ratios: As expected, the average O/E cost ratio for episodes with downstream events that are of high resource, like readmissions or PAC use, are higher than episodes without such events.

Service Utilization: Although the hypothesized positive relationship between a hospital's average predicted episode cost and average episode rates of service use may not be linear or strong as high service use may be comprised of low-cost services relative to higher cost alternative services (consider, for example, the substitution between a high E&M visits per episode rate for regular patient check-ups versus a low but costly adverse event, like emergency surgery), the positive correlations evidenced are in line with the expectations.

Correlations with Other Measures: The relationship between the MSPB Hospital measure's risk-adjusted episode cost and other cost, efficiency, outcome, and quality measures are largely in line with hypothesized and literature-based expectations. Similar to the MSPB Hospital measure, the three Payment & Value of Care measures analyzed are triggered by an index hospitalization and consider standardized amounts. Unlike the MSPB Hospital measure, the episode window for these measures run 30-days from hospitalization – instead of 30-days after hospital discharge and are specific to hospitalizations that have principal discharge diagnoses of Acute Myocardial Infarction, Heart Failure, or Pneumonia. Importantly, these measures also prorate claim payments to their 30-day episode window and consider patient populations that expired, while the MSPB Hospital Measure does neither and these measures differ in their risk adjustment model methods. With these differences, however, we capture an expected positive rank correlation with these condition-specific cost measures. Further, the positive rank correlation between a hospital's average expected episode cost and non-cost measures of inefficiency (e.g. Emergency Department wait time) is in-line with existing literature. The rank correlations with other measures used in the FY2019 HVBP program and the MSPB Hospital measure's average expected cost are also in line with expectations. Literature has found, for example, that hospital acquired infections are associated with higher Medicare costs and this recognition is not new, with CMS ceasing payment for select HAIs in the past. Other literature has also noted the positive relationship between reported patient satisfaction and efficiency outcomes, like shorter stays, lower readmissions, and lower mortality rates, that can influence cost.

Measure performance – Type of Score

Ratio

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

Given that the MSPB Hospital is a claims-based measure, there is no submission method for the measure. Based on the analysis of all IPPS eligible hospitals with at
least 25 episodes for the 2018 performance period, the
MSPB Hospital measure score has the following

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distributional characteristics:

- Mean: 0.99, standard deviation: 0.08
- Median: 0.99
- Min: 0.49, max: 1.68
- Interquartile range spans from 0.94 to 1.03

Benchmark, if applicable
The benchmark is the average (mean) performance on the MSPB Hospital measure of the top 10% of hospitals during the baseline period.

Measure Contact Information

Measure Steward
Centers for Medicare & Medicaid Services

Measure Steward Contact Information
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N/A

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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-131 Medicare Spending Per Beneficiary (MSPB) Hospital

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

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Justification and Notes: Although this measure does not address any of IQR's measurement priorities, it does correspond to the Affordable and Efficiency Meaningful Measures 2.0 area.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes: The MSPB measure compares a hospital's episode costs to the national median hospital's episode costs, both on a risk-adjusted basis. According to MedPAC's 2020 report on Medicare payments, Medicare spending for inpatient care at short-term acute care hospitals amounted to $121 billion, a growing figure. To control costs, MedPAC recommended incentivizing stronger coordination of care to prevent readmissions and other costly hospital episodes, which this measure specifically addressed. For example, hospitals could coordinate with post-acute care providers to reduce adverse events after discharge, or shift post-acute spending to home health.

Does the measure address a quality challenge?
Yes/No: Yes
Justification and Notes Performance data for hospitals on the MSPB measure in 2018 showed substantial variation in scores, suggesting an opportunity for improvement for lower-performing hospitals. In the 20th percentile of performance (where lower is better), hospitals spent 93% of the median hospital, whereas the 80th percentile spent 105% as much as the median hospital – indicating a 13% possible spending reduction if the lowest-performing hospitals were to improve to the level of the highest-performing hospitals. In practice, this would represent tens of billions of dollars in reduced Medicare costs.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes
Justification and Notes: This Measure Under Consideration was endorsed by the National Quality Forum in June 2021.

Can the measure be feasibly reported?
Yes/No: Yes
Justification and Notes: The measure is based on administrative claims that are available electronically. No feasibility issues were reported in prior years of implementation in the HVBP program.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes
Justification and Notes: The Measure Under Consideration, a methodological refinement to the MSPB measure that was historically included in the IQR program, was endorsed by the National Quality Forum in June 2021. The measure was specified for and tested in the hospital care setting, at the facility level of analysis, consistent with the IQR program requirements.

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?
Yes/No: No
Justification and Notes: Over several years of implementation in the HVBP program, and two reviews for endorsement by NQF's Consensus Development Process (CDP), no negative unintended consequences were identified.

MAP Rural Health Advisory Group Input:
Relative priority/utility:

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- There was discussion that this measure is not addressing the needs of a number of rural hospitals; however, the developer clarified that there are some critical access hospitals in the measure
- The measure was removed from IQR to make room for the updated version. This updated version of the measure would go first to HIQR for public reporting, and then eventually replace the MSPB Hospital measure in the HVBP program

Data collection issues:
- None

Calculation issues:
- None

Unintended consequences:
- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.7
1 – 0 votes
2 – 0 votes
3 – 3 votes
4 – 7 votes
5 – 0 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 2.9
1 – 0 votes
2 – 7 votes
3 – 4 votes
4 – 6 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Support for Rulemaking

Summary: What is the potential value to the program measure set? The Medicare Spending per Beneficiary measure was removed from IQR beginning in 2020, in order to reduce duplication with measures in the Hospital Value-Based Purchasing Program (HVBP), where it was retained. By statutory

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requirement, all measures entering the Hospital VBP Program must be implemented for at least one year prior in the Hospital IQR Program. Endorsement of this measure was retained during the last review cycle in June of 2021.

Summary: What is the potential impact of this measure on quality of care for patients? Performance data from prior years of implementation of this measure indicates a substantial opportunity for improvement: there is a considerable range in costs for episodes of care across U.S. hospitals. This measure, one of the only cost measures used in federal quality program reporting, will continue to incentivize hospitals to identify methods of cost savings such as care coordination initiatives and patient safety initiatives to reduce the number of costly adverse events.

Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) noted during the recent National Quality Forum (NQF) review of this measure that the Centers for Medicare and Medicaid Services (CMS) did not provide an adequate justification on why the weighting of all risk-adjusted hospital episodes were changed nor was any rationale provided on the expansion of episodes to include re-hospitalizations within 30 days of discharge of any admission that opens an episode. We are particularly concerned with the inclusion of re-hospitalizations as a trigger episode since the same costs will now be attributed twice to a hospital. Double counting of costs is inappropriate and provides misleading information to providers and patients.

In addition, we continue to question the scientific acceptability of the measure based on the risk model's fit with the unadjusted and adjusted R-squared ranging from 0.11 to 0.67 across the Major Diagnostic Categories. The FAH does not believe that the reasons for this result were adequately addressed and risk adjustment must be improved.

Furthermore, while the FAH appreciates that social risk factors were reviewed, we remain concerned with the risk adjustment approach to determine whether inclusion of social risk factors. The FAH believes that this approach should not consider the identification and testing of social risk factors as supplementary to clinical risk factors. This approach was identified as a concern by the NQF Disparities Standing Committee and developers must begin to include these factors within the testing of the model rather than the approach of "adding on" factors after the model is developed. This type of analysis would assist facilities and others in understanding how their inclusion could impact the model and provide additional information for groups examining this issue such as the NQF and Office of the Assistant Secretary for Planning and Evaluation. Even with testing of the social risk factors after the clinical risk factors, analyses showed that hospitals' measure scores shift when some or all of the social risk factors are applied within the risk model and particularly just over 15% of safety-net hospitals moved above or below the delta. This shift should lead CMS to reconsider inclusion of some or all of the variables in the risk model.

In addition, CMS must address the duplicate reporting of the measure results as these revisions are implemented in either program. The potential for misleading and/or inaccurate information must be

avoided at all costs. As a result, the FAH requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

American Medical Association

The American Medical Association (AMA) is concerned that the changes to equally weight all risk-adjusted hospital episodes by the average ratio of observed to expected costs and expand episodes to include re-hospitalizations within 30 days of discharge of any admission that opens an episode have not been sufficiently justified. No rationale was provided for any of these changes during the recent review by the National Quality Forum or in this submission, which makes it difficult for us to provide input and determine whether we agree or have concerns with the changes. For example, it remains unclear to us whether the expansion to include readmissions will now double count the costs attributed to a hospital.

Premier, Inc.

Premier conditionally supports adoption of this refined measure. CMS should seek endorsement before moving forward with the measure.

American Heart Association

The American Medical Association (AMA) is concerned that the changes to equally weight all risk-adjusted hospital episodes by the average ratio of observed to expected costs and expand episodes to include re-hospitalizations within 30 days of discharge of any admission that opens an episode have not been sufficiently justified. No rationale was provided for any of these changes during the recent review by the National Quality Forum or in this submission, which makes it difficult for us to provide input and determine whether we agree or have concerns with the changes. For example, it remains unclear to us whether the expansion to include readmissions will now double count the costs attributed to a hospital.

In addition, the AMA continues to believe that the current risk adjustment model is not adequate due to the unadjusted and adjusted R-squared results ranging from 0.11 to 0.67 across the Major Diagnostic Categories nor is the measure adequately tested and adjusted for social risk factors. It is unclear to us why the developer would test social risk factors after adjusting for clinical risk factors rather than assessing the impact of both clinical and social risk factors in the model at the same time. These variations in how risk adjustment factors are examined could also impact how each variable (clinical or social) perform in the model and remain unanswered questions. In addition, we note in the information submitted to NQF hospitals’ measure scores shifted when some or all of the social risk factors are applied within the risk model and particularly just over 15% of safety-net hospitals moved above or below the delta.

Furthermore, we ask that the MAP include a condition recommending that the Centers for Medicare and Medicaid Services (CMS) halt reporting of the existing measure including any public release of performance results. Continued use of the existing measure is inappropriate and could produce conflicting information to providers and patients.

As a result, the AMA believes that these concerns must be addressed prior to implementation of this revised measure and requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

Johnson & Johnson

Johnson & Johnson agrees with the MAP's support for rulemaking for this measure. Johnson & Johnson

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agrees with the importance of evaluating and understanding Medicare beneficiaries cost of care. Even more critical is evaluating the value of care provided. Determining the value of care cannot be reduced to the evaluation of its cost. We therefore emphasize the importance of pairing measurement of individual Medicare spending in measures of total cost of care with an appropriate time horizon to understand the true value of diagnostics and treatment – upfront costs to Medicare and patients, if associated with appropriate care, will ideally translate into value via reductions in higher cost treatment. It is critical to ensure that measurement of individual Medicare spending be paired with measures of high-quality care that evaluates whether appropriate evidence-based services that achieve optimal clinical outcomes for patients were provided. Measuring cost and quality of care in the context of meaningful patient-centered measures is critical; this must go beyond evaluating satisfaction with experience of care and evaluate the extent that providers are collaborating with patients on goals of care, that those goals of care were met, and that meaningful patient-reported outcomes (such as quality of life and functional status) and clinical endpoints (survival, reducing disease progression) were achieved. We encourage CMS to explore the extent to which unintended consequences may be a risk, such as incentivizing reductions in access to new therapies. We are concerned that specification changes to the measure that would allow hospital readmissions to trigger new MSPB episodes, where novel therapies will lead to expected readmissions to manage severe treatment adverse events.

American Medical Association

The American Medical Association (AMA) continues to have concerns with how this measure is specified and the inadequate risk adjustment testing. As a result, the AMA believes that these concerns must be addressed prior to implementation of this revised measure and requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

American Hospital Association

The AHA recommends that this measure receive the designation of Conditional Support for Rulemaking. While we understand the statutory language requiring CMS to adopt the measure in the IQR in order for it to be used in the Hospital VBP program, we continue to have concerns regarding duplication and consistency across the programs. Specifically, the proposed revision to this measure would allow readmissions in the 30-day post-discharge episode to trigger a new episode; we do not believe that this detail aligns with the windows used in other measures.

MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Medicare Promoting Interoperability Program for Hospitals, PPS-Exempt Cancer Hospital Quality Reporting Program, Long-Term Care Hospital Quality Reporting Program, Inpatient Rehabilitation Facility Quality Reporting Program, Skilled Nursing Facility Quality Reporting Program

Workgroup
Hospital

Measure Description
This measure tracks the development of new Clostridioides difficile infection among patients already admitted to healthcare facilities, using algorithmic determinations from data sources widely available in electronic health records. This measure improves on the original measure by requiring both microbiologic evidence of C. difficile in stool and evidence of antimicrobial treatment.

Numerator
Healthcare-Associated Clostridioides difficile Infection (HA-CDI):
Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.
HA-CDI 1: must meet BOTH A & B.
A) Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.
B) Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.
HA-CDI 2: must meet BOTH A & B.
A) Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.
B) Administration of oral or intravenous metronidazole within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

Numerator Exceptions
Excluding well baby-nurseries and neonatal intensive care units (NICU).

Denominator
The expected number of HA-CDI based on predictive models using facility- and patient care location data as predictors.

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Denominator Exclusions
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count
Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions
Under investigation, subject to change.

State of development
Specification

State of Development Details
The measure stewards have partnered with several research groups to evaluate HA-CDI in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing.

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Infectious disease

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1. Microbiology records of stool tests for C. difficile, typically from an EHR laboratory information system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

The HA-CDI measure requires linking relevant stool microbiological test results with applicable antimicrobial administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

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What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

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If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
MUCFIFTEEN-533: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

How will this measure be distinguished from other similar and/or competing measures?
The current NHSN measure is based on laboratory results, and C. difficile is typically diagnosed using non-culture based diagnostic tests which have wide variation in sensitivity and in rates of false positives. Creating a surveillance definition that more closely approximates the disease-state requires incorporating clinical decision-making into the measure. The updated measure includes not only the lab test for C. difficile but also the use of an antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the limited and particular therapies used for infections due to C. difficile.

How will this measure add value to the CMS program?
This new measure increases the clinical validity of original measure, and therefore more accurately reflect the presence of clinical infection and quality measurement.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

C. difficile caused 159,463 infections among hospitalized US patients in 2019. (1) Robust surveillance combined with incentives from value-based purchasing resulted in a reduction of 42% between 2015 and 2019 in acute-care hospitals. (1) Further improvements are possible, but aspects of the existing surveillance definition complicate the external reception of the measure and create unintended consequences regarding testing and treatment practices. (2, 3) These issues also challenge the ability to track trends in true infections as organizations alter their practices. Validation studies performed from 2013 -2106 by 6 different states, suggest that the negative predictive value of the metric is low at ~59% indicating that, in addition to potential manipulation of testing practices, many cases are being missed in the reporting process. (4) To address these concerns, CDC's National Healthcare Safety Network (NHSN) proposes a new measure that promotes further improvements in care for patients and reduces unintended consequences.

Creating an improved surveillance definition that more closely approximates the disease-state requires incorporating use of therapy as a proxy for clinical decision-making into the measure. To that end, this new NHSN measure includes not only the lab test for C. difficile but also the use of a specific antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the specific therapies used for infections due to C. difficile. (5)

References

1. Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI
2. Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458
3. Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf
4. Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN
5. McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

Evidence that the measure can be operationalized

There is a proven track record for CMS to obtain this data from NHSN which currently shares facility-level CDI SIRs for hospital IQR program.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

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Evidence of Performance Gap
Analysis forthcoming

Unintended Consequences
It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection. ;It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score
To be determined.

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HA-CDI event, the mean unadjusted cost is ~$50,000 (median $27,000). As an unadjusted, unmatched comparison group, hospitalizations with only a negative stool test for C. difficile had an average cost of ~$26,000 (median ~$11,000). (Unpublished data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019.

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Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
No

If yes, choose all methods that obtained clinician and/or provider input
N/A

Total Number of Clinicians/Providers Consulted
N/A

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
N/A

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

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If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs and EIP projects summer 2021.

Measure performance – Type of Score
Ratio

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Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

HA-CDI performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).

Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HA-CDI events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HA-CDI events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HA-CDI events for the facility using the negative binomial regression model.
3. Divide the number of observed HA-CDI events (1 above) by the number of expected HA-CDI events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HA-CDI events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HA-CDI events for the facility
2. Obtain the adjusted number of observed HA-CDI for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HA-CDI events
4. Obtain the expected number of HA-CDI events
5. Divide the total number of adjusted HA-CDI events (3 above) by the predicted number of HA-CDI events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable

See methods above for calculation of SIR and ARM.

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Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

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Long-Term Measure Steward
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Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: The Measure Under Consideration calculates the observed number of Healthcare-Associated Clostridioides difficile Infections (HA-CDIs) at a health care facility, divided by the number of infections expected based on facility characteristics. Although this measure does not address any of the Hospital Inpatient Quality Reporting (Hospital IQR) Program measurement priorities, it does correspond to the Patient Safety focus within CMS' Meaningful Measures 2.0. There was historically a very similar measure included in the Hospital IQR Program, the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF #1717). However, this measure was removed beginning 2021 in order to reduce duplication with the measure in the Hospital-Acquired Condition Reduction Program (HACRP), where it is retained (CMS, 2018). Adding this measure would-re-introduce the duplication problem identified by CMS in prior reporting years. The MAP should consider whether adding this measure into the IQR program will lead to lead to re-introducing duplication of measures.

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Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes: After several years of implementation of HA-CDI quality measures, a 48 percent decrease in reported HA-CDIs within Acute Care Hospitals was observed from 2015-2020 (Centers for Disease Control and Prevention, 2021). This indicates hospitals have successfully implemented initiatives, such as CDC's guidelines for hand hygiene, that are reducing infection rates (2002). This measure is intended to capture HA-CDI infections more precisely than the existing measure in other hospital programs by only counting those infections among inpatients that have both a positive laboratory test and evidence of an antimicrobial agent administered to the patient two days before or after the positive test result.

Does the measure address a quality challenge?
Yes/No: Yes
Justification and Notes: HA-CDI infections are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDI infections were reported to the CDC. CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures. According to NHSN reports, in 2020 the 20th percentile of performance for acute care hospitals was .182 infections observed/expected, compared to an 80th percentile performance of .762 infections observed/expected, indicating a substantial range in performance.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes
Justification and Notes: In 2021, CMS removed a very similar measure (NQF #1717) from the Hospital IQR Program, choosing to retain the same measure in the HACRP only. Adding this measure to the Hospital IQR Program would re-introduce the duplication of measurement issue identified by CMS as part of that decision.

Can the measure be feasibly reported?
Yes/No: Yes
Justification and Notes: All data elements required to calculate the measure are available in defined fields in electronic data. A similar HA-CDI measure currently implemented in other programs has been successfully submitted by thousands of acute care hospitals for several years.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: No
Justification and Notes: This measure is a specification update to an existing NQF-endorsed measure, #1717. The revised specifications have not been submitted to NQF for endorsement, and reliability and validity testing has not been finalized.

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?
Yes/No: N/A
Justification and Notes: The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test for CDI AND a treatment administered. This update is intended to mitigate instances where a facility or provider might be incentivized not to test for a suspected HA-CDI.

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PAC/LTC Core Concept?
Yes/No: N/A
Justification: N/A

Impact Act Domain
Yes/No: N/A
Justification: N/A

Hospice High Priority Areas
Yes/No: N/A
Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.9
1 – 0 votes
2 – 0 votes
3 – 1 votes
4 – 9 votes
5 – 0 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.5
1 – 0 votes
2 – 2 votes

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3 – 5 votes
4 – 10 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This updated measure is intended to capture HA-CDI infections more precisely than the existing similar measure in other hospital programs by only counting those infections among inpatients that have both a positive laboratory test and evidence of treatment. Although this measure does not address any of the Hospital Inpatient Quality Reporting (Hospital IQR) Program measurement priorities, it does correspond to the Patient Safety focus within CMS' Meaningful Measures 2.0. In a 2018 decision to reduce the number of measures in the program saw the removal of this measure beginning 2021. This measure under consideration is conceptually very similar to the removed measure.

Summary: What is the potential impact of this measure on quality of care for patients?
An HA-CDI infection has serious potential consequences for patients, including death. Nearly 114,000 HA-CDI were reported to the CDC in 2020. The performance of acute care hospitals on the existing HA-CDI measure shows considerable variation in performance: the 20th percentile of performance for acute care hospitals was .182 infections observed/expected, compared to an 80th percentile performance of .762 infections observed/expected. Nevertheless, this performance has improved by 48 percent over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines. MAP provided Conditional Support for Rulemaking, pending NQF endorsement.

Section 3: Public Comments

Federation of American Hospitals
The Federation of American Hospitals (FAH) supports the further refinements to this measure but recommends that the measure with these changes is tested and endorsed by the National Quality Form prior to implementation in this program. In addition, the Centers for Medicare and Medicaid Services must address the duplicate reporting of the measure results as these revisions are implemented in either program. The potential for misleading and/or inaccurate information must be avoided at all costs. As a result, the FAH requests that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

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Premier, Inc.

Premier conditionally supports adoption of the measure. The refined measure improves on existing measures by requiring both evidence of an infection and treatment, which will help to exclude cases resulting from colonization and improve clinical validity of the measure. However, we are concerned that this measure is similar to the existing CDI measure and that adoption will duplicate measurement. We would encourage CMS to clarify a timeline for replacing the existing CDI measure with this refined measure. Additionally, CMS should not move forward with the measure until it has received endorsement.

American Hospital Association

Accurate surveillance of new C. diff infections is critical to pinpointing areas for improvement within hospitals, so the AHA appreciates the revision to this existing measure that would ostensibly enhance the precision of detection. The current C. diff measure is based solely on positive lab results, but the various diagnostic tests used to detect C. diff have a wide variation in sensitivity as well as varying rates of false positives. The lack of comparability across sites limits the utility of quality improvement collaboratives and best practices. This measure, however, would require both microbiologic evidence of an infection as well as evidence of antimicrobial treatment as a proxy for indication of a clinically significant infection. This corroborating evidence is likely to improve the accuracy of the algorithmic determinations of new infections. We look forward to reviewing the results from the reliability and validity testing of this measure to see if that prediction is borne out.

We maintain a few concerns related to this measure that we encourage the CDC and CMS to keep in mind as they monitor the use of this measure. The first is that because this measure would be substantially different from the existing C. Diff measure, a new baseline would have to be established; this would result in a multi-year implementation process, and might raise some issues with duplication of surveillance efforts. In addition, the measure stewards mentioned that there is potential to use FHIR standards to extract information from the electronic health records that providers would them submit through the existing NHSN platform; this platform has experienced user issues in the past, and while we think that FHIR standards could be appropriate for this use, we wonder whether CDC is confident in hospitals' ability to implement these standards in the timeline expected for the implementation of this measure.

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MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program

Hospital Inpatient Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Medicare Promoting Interoperability Program for Hospitals, PPS-Exempt Cancer Hospital Quality Reporting Program

Workgroup

Hospital

Measure Description

This measure tracks the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in electronic health records. This measure includes many healthcare-associated infections not currently under surveillance by the Center for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN). Ongoing surveillance also requires minimal data collection burden for users.

Numerator

Observed number of Hospital-Onset Bacteremia & Fungemia (HOB) events, defined below:
Must meet Bacteremia OR Fungemia criteria (BFC), AND Antimicrobial treatment criteria (ATC).
Bacteremia OR Fungemia criteria (BFC):
Patient of any age has a recognized bacterial or fungal pathogen from a blood specimen collected on the 3rd calendar day of admission or later (where the date of admission to an inpatient location is calendar day 1). The pathogen must not be included on the NHSN common commensal list, and meet EITHER of the following criteria:
1) Pathogen identified by culture of one or more blood specimens, OR
2) Pathogen identified to the genus or species level by non-culture based microbiologic testing (NCT) methods.
Note: if blood is collected for culture within 2 days before, or 1 day after the NCT disregard the result of the NCT and use only the result of the CULTURE to make a BFC determination. If no blood is collected for culture within this time period, use the result of the NCT for BFC determination.
Antimicrobial Treatment Criteria (ATC):
A patent must have been administered at least 1 dose of an intravenous or oral (including all enteral routes) antimicrobial in the window period extending 2 calendar days before and 2 calendar days after the date of blood specimen collection for BFC. The date of blood specimen collection is day 0. Furthermore, if the patient had Bacteremia, only antibiotics are eligible to meet the ATC criteria. Similarly, if the patient has Fungemia, only antifungals are eligible to meet ATC criteria. If a

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patient has both Bacteremia and Fungemia, then either an antibiotic or antifungal can meet the ATC criteria.

Numerator Exceptions

1) Previous matching Present on Admission Bacteremia or Fungemia
If a patient meets BFC but also had a pathogen matching to the same species or genus level identified from a blood specimen by culture or NCT that was collected in the Present on Admission (POA) window, defined as hospital calendar day 2 or earlier (where calendar date of admission to an inpatient location is day 1), then this BFC is excluded from the HOB measure.
If multiple pathogens are identified from the same blood culture or NCT, then a match of any of those pathogens to a POA blood pathogen is sufficient to exclude the BFC from the HOB measure.
2) Previous HOB event
A patient with a previous HOB event is excluded from additional HOB events during the same hospital admission.

Denominator

The expected number of HOB events based on predictive models using facility- and patient care location data as predictors.

Denominator Exclusions

Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts. Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions

Under investigation, subject to change.

State of development

Specification

State of Development Details

Specification: The measure stewards have partnered with several research groups to evaluate HOB in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing:
A) Hospital-Onset Bacteremia & Fungemia Preventability Evaluation (HOPE): Two components

1. Evaluation of sources and preventability of HOB events in ~2400 adult and pediatric patients across 13 hospitals. Results expected summer/fall 2021.
2. HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes, and risk factors for HOB in Cerner Healthfacts and Premier Healthcare Databases (500 hospitals, 18,000,000 admissions). Results expected summer 2021.

B) Becton Dickinson: HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes and cost, risk factors, and surveillance feasibility for HOB in 271 hospitals, 8,000,000 admissions. Results expected summer/fall 2021.
C) Veterans Affairs: HOB definition sensitivity analysis, chart review validation, evaluation of epidemiology, surveillance feasibility in 142 hospitals, 1,700,000 admissions. Results expected summer 2021.

What is the target population of the measure?

All Payer

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Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Infectious disease

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1. Microbiology records of blood cultures and NCT, typically from an EHR laboratory information system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

The HOB measure requires linking relevant microbiological test results for blood cultures and NCT with applicable antimicrobial administration records from the medication administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

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If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

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What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program.

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
MUC2019-19: "National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection Outcome Measure"
MUCFIFTEEN-532MRSA: "National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure"

How will this measure be distinguished from other similar and/or competing measures?
The HOB outcome measure collects the number of bloodstream infections that occur during hospitalization (and not present on admission) due to a broad range of pathogenic bacteria and fungi (in contrast to the narrower MRSA measure), and regardless of whether the infection was attributable to a central line or device (in contrast to the narrower CLABSI measure). Furthermore, the inclusion of evidence of antimicrobial treatment for the HOB measure increases the clinical validity of the measure by acting as a proxy for true infections requiring treatment from the provider. This component may become more valuable as emerging non-culture based microbiologic testing (NCT) become more ubiquitous. These tests may have increased false positive signals or could detect pathogen genetic material that may not correspond to live pathogens causing an ongoing bacteremia or fungemia. Thus, requiring evidence of antimicrobial treatment serves as a proxy for the clinical interpretation of infection by the provider.

How will this measure add value to the CMS program?
The HOB outcome measure includes most to nearly all central-line associated bloodstream infections and MRSA bacteremia, and many more bloodstream infections that cause healthcare associated infections but are not currently under surveillance for quality measurement. Preliminary data suggests a substantial percentage of HOB events are preventable under current infection prevention standards, and we anticipate that use of an HOB outcome measure will encourage innovation to identify new methods for reducing these infections. Furthermore, the HOB measure uses an algorithmic approach to determine events, thus reducing regular data collection burden and subjectivity from event determination. "HOB surveillance could inform broad measures to improve infection control in conjunction with other HAI data, potentially resulting in measurably improved patient outcomes. HOB data collection and reporting burden would likely be low given the ubiquity and functionality of current EHRs, in contrast to NHSN CLABSI and other measures that call for substantial investments of time and effort in manual reviews of healthcare records." (1)
References:

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1) Dantes et al. Hospital epidemiologists' and infection preventionists' opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Multiple justification studies are underway.
An HOB measure is viewed favorably among subject matter experts and users. A survey of 89 researchers in the Society for Hospital Epidemiology of America (SHEA) Research Network found that "Among the majority of SHEA Research Network respondents, HOB is perceived as preventable, reflective of quality of care, and potentially acceptable as a publicly reported quality metric." Furthermore, "Given a choice to publicly report central-line-associated bloodstream infections (CLABSIs) and/or HOB, 57% favored reporting either HOB alone (22%) or in addition to CLABSI (35%) and 34% favored CLABSI alone. (1)
References
1) Dantes et al. Hospital epidemiologists' and infection preventionists' opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540.

Evidence that the measure can be operationalized

The HOB measure leverages sources of data, primarily microbiology and medication administration data, that are already used for many existing CDC National Healthcare Safety Network (NHSN) measures and reported to CMS on a quarterly basis.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

Interim and preliminary analysis from the HOPE study with approximately half the data collected shows approximately 41% of HOB events were considered preventable after expert review. Final results expected summer/fall 2021.

Unintended Consequences

It is possible that providers and facilities may be discouraged from ordering blood cultures or NCT among patients that are later into their hospitalization when they suspect an infection.

Outline the clinical guidelines supporting this measure

N/A

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Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure:
Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Denominator Size
N/A

Estimate of Annual Improvement in Measure Score
To be determined.

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure
N/A

Estimate of Average Cost Savings Per Event
For hospitalizations with an HOB event, the mean unadjusted cost is ~$83,000 (median $44,000). As an unadjusted, unmatched comparison group, hospitalizations with negative blood cultures had an average cost of ~$45,000 (median $26,000). (Data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019

Patient and Provider Perspective

Meaningful to Patients
No

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Was input collected from patient and/or caregiver?
N/A

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians
N/A

Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys

Total Number of Clinicians/Providers Consulted
76

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
41

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

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Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs project summer 2021

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs project summer 2021

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs project summer 2021

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs project summer 2021.

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Validity Testing Statistical Result

Planned for Veterans Affairs project summer 2021.

Validity Testing Interpretation of Results

Planned for Veterans Affairs project summer 2021.

Measure performance – Type of Score

Ratio

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

HOB performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).

1. Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HOB events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:
2. Identify the number of unique HOB events for a given time period by adding the total number of observed events across the facility.
3. Calculate the number of expected HOB events for the facility using the negative binomial regression model
4. Divide the number of observed HOB events (1 above) by the number of expected HOB events (2 above) to obtain the SIR.
5. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HOB events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HOB events for the facility
2. Obtain the adjusted number of observed HOB for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HOB events
4. Obtain the expected number of HOB events
5. Divide the total number of adjusted HOB events (3 above) by the predicted number of HOB events (4 above) to obtain the ARM.

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6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable
See description of SIR and ARM above.

Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
Raymund Dantes
1600 Clifton Rd
Atlanta, GA 30333
vic5@cdc.gov
800-232-4636

Long-Term Measure Steward
Centers for Disease Control and Prevention

Long-Term Measure Steward Contact Information
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Atlanta, GA 30333
aqb4@cdc.gov
800-232-4636

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. Although this measure does not address any of IQR's measurement priorities, it does correspond to the Patient Safety Meaningful Measures 2.0 area. There are two measures that historically were in included in IQR, whose measure result would be

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reflected in this proposed measure: (1) the NHSN MRSA bacteremia measure, and (2) the NHSN CLABSI measure. However, both were removed from IQR beginning in 2020, in order to reduce duplication with measures in the Hospital-Acquired Condition Reduction Program (HACRP), where they were retained. Adding this measure would-re-introduce the duplication problem identified by CMS in prior reporting years. The MAP should consider whether adding this measure into the IQR program will lead to re-introducing duplication of measures.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: There is evidence that the HOB tracked by this outcome measure can be prevented by hospitals; one 2017 study by Dantes et al estimated that 49% of HOB infections were potentially preventable, and a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists estimated that 50 percent or more of HOBs could be prevented, with a variety of hospital practices identified that could reduce HOBs. In an unpublished analysis of healthcare data by the measure submitter, hospitalizations with an HOB were found to be nearly twice as expensive as those without (average cost of $83,000 compared to $45,000).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: HOB are common infections, especially relative to other infections currently measured in quality reporting programs: for example, a 2015 study by Rock et al found that HOB infections were 17 times as likely to be observed in an ICU compared to CLABSI infections. The same study concluded that a change in HOB rate has a greater power to discriminate between ICU performance than CLABSI rates. Contracting an HOB leads to a greatly increased risk of mortality, as found by Lambert et al, 2011. The developer also cites preliminary results from the HOPE study analysis in which approximately 41 percent of HOB events were considered preventable after expert review. The developer notes that final study results are expected summer/fall 2021. Although performance data for this measure are not yet available, a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists found that 54 percent agreed that the measure concept would reflect quality of care at a hospital.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: In 2020, CMS removed a suite of infection surveillance measures from the IQR program, choosing to retain them in the Hospital-Acquired Condition Reduction Program (HACRP) only. Adding this measure to the IQR program may re-introduce the duplication of measurement issue identified by CMS as part of that decision. The MAP should consider whether adding this measure into the IQR program will lead to re-introducing duplication of measures.

Can the measure be feasibly reported?
Yes/No: Yes

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Justification and Notes: All data elements are available in defined electronic fields; no data abstraction is required.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is specified for the appropriate care setting, level of analysis, and patient population. However, no reliability or validity testing of the measure result has been conducted, and the measure has not been reviewed for endorsement by the National Quality Forum.

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?

Justification and Notes: Although the measure has not been implemented or tested in a healthcare facility, one possible unintended consequence that the developer identified is that the measure may discourage providers and hospitals from testing patients where they suspect a bacteremia or fungemia infection.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.

Average: 3.8

1 – 0 votes

2 – 1 votes

3 – 1 votes

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4 – 8 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.5
1 – 0 votes
2 – 2 votes
3 – 5 votes
4 – 10 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. Although this measure does not address any of the Hospital Inpatient Quality Reporting (Hospital IQR) Program measurement priorities, it does correspond to the Patient Safety focus within CMS' Meaningful Measures 2.0. In a 2020 decision to reduce the number of measures in the program saw the removal of several infection surveillance measures; this Measure Under Consideration is conceptually very similar to those.

Summary: What is the potential impact of this measure on quality of care for patients?
This Measure Under Consideration tracks a group of very common, and potentially lethal, hospital-acquired infections. Hospitalizations where these conditions were identified were nearly twice as expensive as the average hospital stay, indicating high resource utilization needed to treat these conditions. Despite the common and costly nature of these infections, studies and surveys estimate that nearly half of these infections are preventable by the hospital. Incentivizing the adoption of infection control practices that would reduce the incidence of these conditions would present a substantial benefit to both patients and the health care system. MAP provided Conditional Support for Rulemaking, pending NQF endorsement.

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Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports measures that ensure patient safety and reduction of infections for individuals receiving care during an inpatient stay but measures must be based on robust evidence and produce reliable and valid results. This measure does not currently meet any of these minimum requirements nor has it received endorsement by the National Quality Forum. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

Premier, Inc.

Premier conditionally supports adoption of this measure. While we agree that this measure addresses some healthcare-associated infections not currently under NHSN surveillance, we are concerned that it may duplicate existing measurement under the HAC Reduction Program (e.g., CLABSI and MRSA measures). We encourage CMS to develop a strategy that ensures broader surveillance of HAIs without increasing burden on hospitals or duplication of existing efforts. Additionally, CMS should not move forward with the measure until it has received endorsement.

Johnson & Johnson

Johnson & Johnson agrees with the MAP's recommendation of conditional support for this measure. This measure encourages hospitals to take precautions that prevent hospital-onset bacteremia and fungemia. By holding hospitals accountable for the development of new bacteremia and fungemia infections, this measure promotes patient safety, improves quality outcomes and seeks to contain avoidable infections and excess costs. In general, Johnson & Johnson supports measures that incentivize management and reduction of hospital-onset infections and addresses Hospital-Acquired Condition Reduction Program measurement priorities.

American Hospital Association

We appreciate the CDC's work to improve the accuracy of measures assessing hospital-acquired conditions by coupling clinical information from electronic health records with lab tests. However, we urge CMS to exercise caution in adopting this measure, as the concept of a broad-based bacteremia measure carries inherent risks and trade-offs.

First, this measure of new bacteremia and fungemia infections would include nearly all CLABSIs and MRSA infections, and thus would overlap with existing measures evaluating these occurrences. CMS needs to ensure that measure sets are consistent and complementary, and during the MAP meeting representatives noted that the agency does not anticipate removing the current measures simultaneously with the adoption of this new measure. We worry that this will result in double-counting of infections or inconsistent calculation of performance across disparate measures.

A related issue with introducing a new HAC measure is the lack of baseline. Because the measure is not entirely comparable to existing HAC measures, an entirely new baseline would have to be established. This would necessitate a multi-year implementation process, further muddying the data used for the HAC program. These logistical concerns do not necessarily detract from this measure's usefulness, but we do encourage CMS to thoughtfully construct a plan and educational approach for the use of this and other HAC measures.

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Finally, we are concerned that a measure assessing incidence of any bacteremia or fungemia on the NHSN common commensal list may not necessarily enhance quality improvement efforts. Given the evidence presented to the workgroup, we are not sure whether all pathogens are equally preventable, and whether this topic is the right focus for a program that has been evolving as best practices and improvement collaboratives have evolved as well. Because of these concerns, we recommend that the measure developer work more with stakeholders to analyze results of the alpha testing period as well as the potential use of this measure in future CMS programs—and this may be the far future, considering the lengthy implementation process likely necessary for this measure.

Intermountain Healthcare

Intermountain Healthcare expresses concern about further action on this measure in light of the significant new burden that would be imposed for hospital infection preventionists at a time when pandemic conditions have already taken a significant toll on this element of the workforce. Intermountain also notes that NHSN's definition of inpatient status is at odds with the definition used by CMS claims and will create significant burden to adhere to specifications as currently proposed.

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MUC2021-104 Severe Obstetric Complications eCQM

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Inpatient Quality Reporting Program, Medicare Promoting Interoperability Program Hospitals

Workgroup
Hospital

Measure Description
Proportion of patients with severe obstetric complications which occur during the inpatient delivery hospitalization.

Numerator
Inpatient hospitalizations for patients with severe obstetric complications occurring during the delivery hospitalization (not present on admission) including the following:

- Severe maternal morbidity diagnoses (see list below)
- Severe maternal morbidity procedures (see list below)
- Discharge disposition = expired
- ICU length of stay greater than 12 hours at any time during the encounter
- Serum creatinine = 2 mg/dL
- PaO2 < 60 mmHg
- Platelet count < 100 10^3/uL

Severe Maternal Morbidity Diagnoses:

- Cardiac
  - Acute heart failure
  - Acute myocardial infarction
  - Aortic aneurysm
  - Cardiac arrest/ventricular fibrillation
  - Heart failure/arrest during procedure or surgery
- Hemorrhage
  - Disseminated intravascular coagulation
  - Shock
- Renal
  - Acute renal failure
- Respiratory
  - Adult respiratory distress syndrome
  - Pulmonary edema
- Sepsis
- Other OB

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    - Air and thrombotic embolism
    - Amniotic fluid embolism
    - Eclampsia
    - Severe anesthesia complications
- Other Medical
    - Puerperal cerebrovascular disorder
    - Sickle cell disease with crisis

Severe Maternal Morbidity Procedures:

- Blood transfusion
- Conversion of cardiac rhythm
- Hysterectomy
- Temporary tracheostomy
- Ventilation

Numerator Exceptions

N/A

Denominator

Inpatient hospitalizations for patients delivering stillborn or live birth with = 20 weeks, 0 days gestation completed.

Denominator Exclusions

Inpatient hospitalizations for patients with trauma complicating childbirth diagnoses.

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

Alpha testing has been completed for the Severe Obstetric Complications eCQM, which consisted of virtual EHR walkthroughs with nine healthcare pilot sites consisting of 27 individual hospitals. EHR walkthroughs included site EHR experts, report writers, and clinical leads to assess feasibility of the data elements necessary to define the measure specifications. Alpha testing included assessment of clinical and documentation workflows compared to measure intent, assessment of data element availability and accuracy, and assessment of use of data standards to support the completion of the Feasibility Scorecard.

Beta testing consists of testing of the Measure Authoring Tool (MAT) specifications, including value sets, with recruited hospitals to further establish the feasibility and validity of each of the data elements as well as the validity of the outcome. In Beta Testing, we assessed the accuracy of the data extracted from the EHR using the MAT specifications by comparing the data values to values identified through medical record abstraction. Additionally, we confirmed the accuracy of the outcome through clinical medical record review. Beta testing was conducted with data from eight healthcare test sites and 25 hospitals using three different EHR systems: EPIC, Cerner, and Meditech.

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Please see the attached summary document for results.

- ePC07 Testing Summary MUC Submission 05.11.2021 Updated 10.08.2021
- SevereObstetricComplications eCQM Measure Results MUC Submission 10.08.2021

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Obstetrics/gynecology

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Electronic Clinical Data (non-EHR); Electronic Health Record

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
This measure uses electronic health record and electronic clinical data to define all components of the measure: measure denominator, measure numerator, exclusions, risk adjustment variables, and stratification variables.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
Epc 07

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What is the endorsement status of the measure?

Never Submitted

NQF ID Number

N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2022

Submitter Comments

(Pertaining to row 087-088 above). The goal of risk adjustment is to account for patient-level factors that are clinically relevant, have strong relationships with the outcome, and are outside of the control of the reporting entity, without obscuring important quality differences. This measure risk adjusts for case mix differences among hospitals based on clinical status of the patient and other patient characteristics at the time of admission including a Housing Instability variable. In addition, this measure intends to consider stratifying measure results by race and ethnicity. Research and prevalence data have indicated considerable racial and ethnic disparities in maternal outcomes. Stratification of results by race/ethnicity will enhance interpretability of results and will provide useful and important information for hospitals seeking to improve quality outcomes for patients and for patients making decisions about care.

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

Yes

If eCQM, enter Measure Authoring Tool (MAT) number

1028

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

Yes

If eCQM, does any electronic health record (EHR) system tested need to be modified?

No

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If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program.

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Although the United States (US) is one of the most developed countries, there continues to be a staggering increase in the number of pregnant women who suffer from complications associated with Severe Maternal Morbidity (SMM). It has been found that rates of SMM are steadily increasing in the US [1]. Approximately 144 per 10,000 women hospitalized for delivery have experienced SMM, including hemorrhage, embolism, hypertension, stroke, and other serious complications [1]. Considerable racial and ethnic disparities exist; Black women and Hispanic women are at considerably higher risk for

developing these complications and experiencing maternal mortality than are Non-Hispanic White women [2,3]. Additionally, recent maternal mortality data from 2018 reveal that 658 women died from maternal causes, resulting in a rate of 17.4 deaths per 100,000 live births, with 77% of the deaths attributed to direct obstetric causes like hemorrhage, preeclampsia, obstetric embolism, and other complications [4].

Per report from the Center for Disease Control and Prevention (CDC), the overall rate of SMM increased almost 200%, from 49.5 per 10,000 delivery hospitalizations in 1993 to 144.0 per 10,000 delivery hospitalizations in 2014 [1]. This increase has been mostly driven by blood transfusions, which increased by almost 400% in that period. Excluding blood transfusions, there has been a 22.4% increase in SMM, from 28.6 in 1993 to 35.0 in 2014 [5]. Increasing rates of SMM are resulting in increased healthcare costs and, longer hospitalization stays [6-9].

National evaluation of hospitals' performance on maternal morbidity and mortality is limited because there are currently no maternal morbidity or obstetric complications outcome measures in national reporting programs. Current quality measures related to pregnancy and maternal health proposed for or in public reporting programs are largely process measures (e.g., Maternity Care: Post-partum Follow Up and Care Coordination) and outcome measures related to delivery type (e.g., PC-01 Elective Delivery). The high maternal mortality and morbidity rates in the United States present unique opportunities for large-scale quality measurement and improvement activities. Statistics on preventability vary but suggest that a considerable proportion of maternal morbidity and mortality events could be prevented [10,11] .

This measure will therefore assist in the discovery and understanding of SMM outcomes and disparities in maternal outcomes, which can lead to improvements in the safety and quality of maternal care necessary to reduce SMM and mortality rates.

1. Severe maternal morbidity in the United States. (2017) https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html

2. Leonard SA, Main EK, Scott KA, Profit J, Carmichael SL. Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology. 2019;33:30-36.

3. Petersen EE, Davis NL, Goodman D, et al. Vital signs: pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report. 2019;68(18):423.

4. Hoyert DL, Miniño AM. Maternal mortality in the United States: changes in coding, publication, and data release, 2018. 2020.

5. Rates in severe morbidity indicators per 10,000 delivery hospitalization. (2020, February 10). From https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.html

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6. Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.

7. 7.Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology.

8. Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine.

9. Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019.

10. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education. 2019;40(36):8.2

11. Geller SE, Rosenberg D, Cox SM, et al. The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology. 2004;191(3):939-944

Evidence that the measure can be operationalized

This measure is based on data elements that are in structured fields and extractable from the electronic health record (EHR). CMS intends to operationalize this measure as an eCQM in the acute care inpatient hospital population using data consistently captured during care. Utilizing EHR data for quality improvement and measurement efforts has several advantages compared to claims data alone, because the data tend to be clinically rich and produced in real time [12]. The Severe Obstetric Complications eCQM will help address the patient safety priority area under the Meaningful Measures 2.0 Framework.

Please see the summary documentation and Feasibility Scorecards, attached, for evidence of data source availability.

12. OPTUM. The Benefit of using both claims data and electronic medical record data in health care analysis. 2012

How is the measure expected to be reported to the program?

eCQM

Feasibility of Data Elements

All data elements are in defined fields in a combination of electronic sources.

Evidence of Performance Gap

The high maternal mortality and morbidity rates in the United States present unique opportunities for large-scale quality measurement and improvement activities. Statistics on preventability vary but suggest that a considerable proportion of maternal mortality and morbidity events could be prevented. A 2019 report from 14 maternal mortality review committees conducting a thorough review of pregnancy-related deaths determined that 65.8% of them were preventable [10]. Additionally, a study that examined preventability of pregnancy-related death, women with near-miss morbidity, and those with severe morbidity found that 40.5% of deaths, 45.5% of near miss morbidity, and 16.7% of other

severe morbidities were preventable [11]. Moreover, there is also evidence that there is variability in SMM rates among hospitals. Using the CDC definition of SMM, the US median rate was 1.4% and the highest hospital rate was 12.2% [18].

Current quality measures related to pregnancy and maternal health proposed for or in public reporting programs are largely process measures (e.g., Maternity Care: Post-partum Follow Up and Care Coordination) and outcome measures related to delivery type (e.g., PC-01 Elective Delivery), but there is a lack of outcome measures in this space.

There are also numerous state agencies, private and/or non-profit organizations, and collaboratives that have spearheaded maternal health and quality improvement initiatives. For instance, the Alliance for Innovation in Maternal Health (AIM) developed evidence-based patient safety bundles to address leading causes of SMM, like obstetric hemorrhage and hypertension. The CDC Perinatal Collaboratives also support various state-based efforts to promote high quality maternal care. The CMQCC created the Maternal Data Center (MDC) for hospitals with Labor and Delivery units in California, Oregon, and Washington [15]. The MDC allows hospital performance regional and statewide comparisons. Overall, such quality metrics do not currently cater to a national population because there is extensive variation and timing delays in the widespread adoption and implementation of safety protocols in obstetric care across states [16,19]. Moreover, data examining the nationwide implementation of these resources are not widely available [20]. Therefore, the development of a maternal morbidity outcome measure addresses a national measurement gap that can build on learnings from existing maternal health initiatives and measures.

10. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education. 2019;40(36):8.2

11. Geller SE, Rosenberg D, Cox SM, et al. The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology. 2004;191(3):939-944

12. OPTUM. The Benefit of using both claims data and electronic medical record data in health care analysis. 2012

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14. CDC. User guide to the 2017 fetal death public use file. Atlanta, GA: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2017. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/ Dataset_Documentation/DVS/fetaldeath/2017FetalUserGuide.pdf

15. California Maternal Quality Care Collaborative (CMQCC). Who We Are. Retrieved from https://www.cmqcc.org/who-we-are

16. Main EK. Reducing maternal mortality and severe maternal morbidity through state-based quality improvement initiatives. Clinical obstetrics and gynecology. 2018;61(2):319-331.

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17. American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine. (2016, September 01). Severe maternal morbidity: Screening and review. American Journal of Obstetrics & Gynecology, 215(3), B17-B22. http://dx.doi.org/https://doi.org/10.1016/j.ajog.2016.07.050'

18. Deadly Deliveries: Childbirth complication rates at maternity hospitals. https://www.usatoday.com/maternal-mortality-harm-hospital-database/

19. Lenfant C. Clinical research to clinical practice—lost in translation? New England Journal of Medicine. 2003;349(9):868-874.

20. Maher-Griffiths C. Maternal Quality Outcomes and Cost. Critical Care Nursing Clinics. 2019;31(2):177-193.

Unintended Consequences

Measuring obstetric complication outcomes based on EHR data may cause a shift in a hospital's resources to support EHR data extraction and reporting, and away from other functions. Also, although the measure numerator definition is broad, hospitals may potentially focus on complications captured in the measure, while dismissing other complications not currently measured but that are important, as well.

Outline the clinical guidelines supporting this measure

The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend identifying potential cases of severe maternal morbidity for further review, with a focus on outcomes and complications, and consider this an important step toward promoting safe obstetric care [17].

This measure can lead to better quality of care for pregnant women. Severe maternal morbidity events are often avoidable through appropriate care, monitoring, and early intervention. Implementation of this measure would identify patients who experience severe maternal morbidity and mortality in the hospital inpatient setting and incentivize hospitals to implement clinical workflows that facilitate evidence-based management to reduce the likelihood of these events. This measure may result in fewer patients experiencing adverse obstetric events, and thereby improve patient outcomes and experience, prevent longer lengths of stay, lower medical costs, and decrease patient mortality.

17. American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine. (2016, September 01). Severe maternal morbidity: Screening and review. American Journal of Obstetrics & Gynecology, 215(3), B17-B22. http://dx.doi.org/https://doi.org/10.1016/j.ajog.2016.07.050'

Were the guidelines graded?

No

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

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Estimated Impact of the Measure: Estimate of Annual Denominator Size

We Intend to include deliveries performed in acute care inpatient settings nationally. The CDC estimated 3,745,540 live births in the United States in 2019 [13]. In 2017, approximately 23,000 fetal deaths (stillbirths) were reported in the United States [14]. This measure intends to include both live and still births.

13. Hamilton BE, Martin JA, Osterman MJK. Births: Provisional data for 2019. Vital Statistics Rapid Release; no 8. Hyattsville, MD: National Center for Health Statistics. May 2020. Available from: https://www.cdc.gov/nchs/data/ vsrr/vsrr-8-508.pdf.

14. CDC. User guide to the 2017 fetal death public use file. Atlanta, GA: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2017. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/ Dataset_Documentation/DVS/fetaldeath/2017FetalUserGuide.pdf

Estimate of Annual Improvement in Measure Score

Until this measure is implemented, it is challenging to estimate annual improvement in absolute terms. However, research has indicated many pregnancy related deaths and morbidity events are avoidable. A 2019 report from 14 maternal mortality review committees conducting a thorough review of pregnancy-related deaths determined that 65.8% of them were preventable [10]. Additionally, a study that examined preventability of pregnancy-related death, women with near-miss morbidity, and those with severe morbidity found that 40.5% of deaths, 45.5% of near miss morbidity, and 16.7% of other severe morbidities were preventable [11].

Additionally, several initiatives have shown promise in reducing maternal morbidity events. For example, since the inception of the California Maternal Quality Care Collaborative (CMQCC), focused on metrics and toolkits to improve maternal outcomes, the maternal mortality rate in California has declined by 55% between 2006 and 2013 [15]. The CMQCC obstetric hemorrhage collaborative resulted in a 20.8% reduction in SMM in California hospitals compared with the 1.2% reduction in SMM among nonparticipating hospitals [16].

10. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education. 2019;40(36):8.2

11. Geller SE, Rosenberg D, Cox SM, et al. The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology. 2004;191(3):939-944

15. California Maternal Quality Care Collaborative (CMQCC). Who We Are. Retrieved from https://www.cmqcc.org/who-we-are

16. Main EK. Reducing maternal mortality and severe maternal morbidity through state-based quality improvement initiatives. Clinical obstetrics and gynecology. 2018;61(2):319-331.

Type of Evidence to Support the Measure

Clinical Guidelines; Other: Clinical expertise, including TEP, technical advisory panel, patient work group, and clinical consultants

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Is the measure risk adjusted, stratified, or both?

Risk adjusted; Stratified

Are social determinants of health built into the risk adjustment model?

Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event

The costs associated with delivery complications are shown to be high. Investigators evaluating costs for women with a live inpatient birth in 2013 calculated a 37% increase in delivery hospitalization costs for women experiencing severe maternal morbidity (SMM) over those without SMM among commercially insured women ($20,380 versus $14,840), and a 47% increase in delivery costs for women experiencing SMM over those without SMM among women insured with Medicaid ($10,134 versus $6,894) [5]. The differential in costs was even higher in two studies using the Agency for Healthcare Research and Quality's (AHRQ's) Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample. These studies, one using 2011 to 2012 data [6] and the other using 2012 to 2014 data [7], calculated average risk-adjusted hospital costs (not including physician costs) for SMM during delivery hospitalizations at over two times greater for patients with any SMM compared to patients with no SMM, 5.5 times the cost if the patient had two or more SMM events [7], and over 10 times the cost with five or more SMM events [6]. Costs are incurred due to the treatment required by SMM events and the impact on hospital lengths of stay; Premier's Bundle of Joy™ Report (2019) found that women with SMM delivering vaginally have hospital stays that are 70% longer than women with vaginal deliveries experiencing no SMM, and costs that are almost 80 percent higher [9].

1. Severe maternal morbidity in the United States. (2017) https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html
2. Leonard SA, Main EK, Scott KA, Profit J, Carmichael SL. Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology. 2019;33:30-36.
3. Petersen EE, Davis NL, Goodman D, et al. Vital signs: pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report. 2019;68(18):423.
4. Hoyert DL, Miniño AM. Maternal mortality in the United States: changes in coding, publication, and data release, 2018. 2020.
5. Rates in severe morbidity indicators per 10,000 delivery hospitalization. (2020, February 10). From https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.html
6. Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.
7. Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology.
8. Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine.
9. Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019.

Cost Avoided Annually by Medicare/Provider

Unable to determine.

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Source of Estimate
Cost estimates are referenced from the following source(s):

Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.

Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology. 2018;35(13):1287-1296

Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine. 2020;173(11_Supplement): S59-S62
Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019

Year of Cost Literature Cited
Cost estimates are from all U.S. delivery hospitalizations occurring from 2011-2012 [6]; live inpatient births from calendar year 2013 [5]; delivery hospitalizations from 2012 to 2014 [7]; and deliveries for women from 2008 through 2018 [9].

5. Rates in severe morbidity indicators per 10,000 delivery hospitalization. (2020, February 10).From https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.html

6.Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.

7.Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology.

8. Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine.

9. Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019.

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives; Working groups

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patient/caregiver representatives were engaged a total of four times to date, during measure conceptualization and following initial Beta testing. Patient/caregiver representatives provided valuable input on measurement goals, initial measure specification, and outcome and risk adjustment considerations. We intend to engage patient/caregiver representatives one to three additional times for

presentation of final measure results and finalization of measure specifications.

Total Number of Patients and/or Caregivers Consulted

10

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups

1:2

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions

All ten patient/caregiver representatives have expressed strong support for the measure concept and indicated the importance of a measure assessing maternal outcomes, both to improve care and inform care decisions.

Burden for Patient: Does the measure require survey data from the patient?

No

If yes, what is the estimated time to complete the survey?

N/A

If yes, what is the frequency of requests for survey data per year?

N/A

If yes, are the survey data to be collected during or outside of a visit?

N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?

Yes

If yes, choose all methods that obtained clinician and/or provider input

Working groups; Standard TEP

Total Number of Clinicians/Providers Consulted

13

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care

13

Burden for Provider: Was a provider workflow analysis conducted?

Yes

If yes, how many sites were evaluated in the provider workflow analysis?

9

Did the provider workflow have to be modified to accommodate the new measure?

No

If yes, how would you describe the degree of effort?

N/A

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Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
77

Measure Testing Details

Reliability Testing Interpretation of Results
Overall, the study revealed the measure to have excellent data element agreement.

Measure score reliability results with signal-to-noise testing indicated excellent reliability.

See attached summary documents for detailed results.

Type of Reliability Testing
Measure Score Reliability, Data Element Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise; IRR (Inter-rater reliability)

Reliability Testing Sample Size

Data element reliability testing has been completed for 15 individual hospitals. This includes 1 system of 10 hospitals and 5 individual hospitals. We reviewed 30-36 charts at each of the individual hospitals and 3-4 charts for each hospital in the system (6 test sites).

Measure score reliability testing was conducted with data from 25 hospitals. This includes 1 health system with 10 hospitals, 1 health system with 9 hospitals, and 6 individual hospitals (8 test sites).

Reliability Testing Statistical Result
Percent agreement for the data element reliability and signal-to-noise ratio was used to test measure score reliability.

Overall, the data element agreement rate for all six sites was 90.4%.

Signal-to-noise reliability was conducted for two outcomes. Signal-to-noise reliability results for Any Severe Obstetric Complications ranged from 0.982-0.997 with a mean of 0.99 (0.005 SD). Signal-to-noise reliability results for Severe Obstetric Complications Excluding Blood Transfusion Only Cases ranged from 0.916-0.983 with a mean of 0.95 (0.023 SD).

See attached summary documents for detailed results.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

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If yes, specify the number of cases and the percentage of providers

30 to 36 sampled cases per pilot site (30-36 charts at each of the individual hospitals and 3-4 charts for each hospital in the system). 100% of the pilot sites met the minimum denominator requirement.

Type of Validity Testing

Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis

Correlation; Gold Standard Comparison; Other: Gold standard comparison and face validity will be assessed at the completion of testing.

Validity Testing Sample Size

Validity testing has been completed for 15 individual hospitals. This includes 1 system of 10 hospitals and 5 individual hospitals. 30-36 charts were reviewed at each of the individual hospitals and 3-4 charts for each hospital in the system.

Validity Testing Statistical Result

Overall, the data element agreement rate for all 3 sites was 90.4%.

For measure score validity we calculated positive predictive value (PPV), as well as sensitivity, specificity, and negative predictive value (NPV), and kappa scores. The PPV over 6 test sites (with 15 hospitals) was very high at 94.74%. Sensitivity overall was 100%, specificity was 90.48%, and NPV was 100%. The overall agreement rate was 91.2% with a kappa score of .881.

See attached summary documents for detailed results.

Validity Testing Interpretation of Results

The overall data element agreement rate indicates excellent agreement.

Measure score validity testing indicates high positive and negative predictive value, as well as high sensitivity and specificity, and excellent measure agreement.

See attached summary document for detailed results.

Measure performance – Type of Score

Other: We also intend to consider displaying as rate per 10,000 deliveries

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

See attached summary document for detailed results.

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Benchmark, if applicable

N/A

Measure Contact Information

Measure Steward

The Joint Commission

Measure Steward Contact Information

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Section 2: Preliminary Analysis – MUC2021-104 Severe Obstetric Complications eCQM

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: This measure fulfills a high-priority area for the Hospital Inpatient Quality Reporting Program (outcome eCQMs) and addresses the Meaningful Measures area of patient safety. The Hospital IQR program currently includes one structural measure related to maternal morbidity; however, the Maternal Morbidity Structural Measure assesses whether hospitals participate in a perinatal quality improvement collaborative and does not include information on patient outcomes.

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Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This measure is an outcome measure assessing the proportion of patients with severe obstetric complications during an inpatient delivery hospitalization. The overall rate of severe maternal morbidity (SMM) was 139.7 per 10,000 deliveries in the U.S. between 2016 and 2017 (Brown et al., 2020). One population-based cohort study also found a higher risk of infant death among live births with SMM compared to live births without SMM (relative risk = 2.93) (Aoyama et al., 2020).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: Severe maternal morbidity (SMM) refers to unexpected outcomes of labor and delivery with severe consequences to a woman's health (Centers for Disease Control and Prevention, 2021). In the U.S., SMM rates have increased from 49.5 to 139.7 per 10,000 deliveries in the U.S. from 1993 to 2017 (CDC, 2021; Brown et al., 2020). SMM rates are also elevated in minority populations (225.7 vs. 104.7 per 10,000 deliveries in non-Hispanic Black individuals vs. non-Hispanic White individuals) (Brown et al., 2020). A case-control study of pregnancy-related deaths found that 40.5% of deaths, 45.5 percent of near-miss morbidities, and 16.7 percent of other severe morbidities were preventable (Geller et al, 2004).

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: The Hospital IQR Program currently includes one measure assessing hospital participation in perinatal quality improvement initiatives, but the measure does not directly address patient outcomes. As part of the developer submission, the developer noted that current maternal health measures used in public reporting are largely process measures or outcome measures related to delivery type, but there are no measures directly addressing morbidity and obstetric complications.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The developer shared that this measure is an eCQM that utilizes data elements in structured fields extractable from the electronic health record and consistently captured during care. The measure was alpha tested with nine healthcare pilot sites consisting of 27 individual hospitals and received an average feasibility rating of 98%.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes

Justification and Notes: The proposed measure is specified at the facility level and is intended to be used in the hospital inpatient acute care setting, which aligns with the proposed program (Promoting Interoperability). This measure has not been submitted for NQF endorsement but has been tested for reliability and validity in nine pilot sites to date with sufficient measure outcome agreement (91.2%,

kappa score 0.881) and a data element agreement rate of 90.4%.

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?
Yes/No: No

Justification and Notes: The measure is new and is not currently being used. The developer identified the following potential unintended consequences with the deployment of the measure. Specifically, measuring complications based on EHR data may cause hospitals to shift reports from other QI functions to EHR data extraction and reporting. Further, while the measure numerator is broad, hospitals may potentially focus on complications captured in the measure, while dismissing other complications not currently measured but that are important, as well.

PAC/LTC Core Concept?
Yes/No: N/A

Justification: N/A

Impact Act Domain
Yes/No: N/A

Justification: N/A

Hospice High Priority Areas
Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- None

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 votes
2 – 0 votes
3 – 0 votes
4 – 10 votes
5 – 1 votes

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MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This measure is essential for reducing disparities in thinking about ways to stratify by certain subpopulations
- There needs to be appropriate access to care to prevent/address these complications and not clear whether this measure will help elucidate these access issues

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity

Average: 4.4

1 – 0 votes

2 – 0 votes

3 – 0 votes

4 – 12 votes

5 – 7 votes

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?

This newly developed measure is an outcome eCQM, a high priority area for the Hospital IQR Program, and it addresses the Meaningful Measures area of patient safety. If included, this measure would be the only outcome measure in Hospital IQR that directly measures maternal morbidity and obstetric complications. MAP did raise concerns about the sample size for testing of the measure.

Summary: What is the potential impact of this measure on quality of care for patients?

Severe maternal morbidity (SMM) rates have increased from 49.5 to 139.7 per 10,000 deliveries in the U.S. from 1993 to 2017, and racial disparities in SMM persist (225.7 vs. 104.7 per 10,000 deliveries in non-Hispanic Black individuals vs. non-Hispanic White individuals) (CDC, 2021; Brown et al., 2020). Complications are also associated with higher risk of infant death (Aoyama et al., 2020). However, an estimated 40.5% of pregnancy-related deaths, 45.5% of near-miss morbidities, and 16.7% of other severe morbidities are preventable (Geller et al, 2004).

This measure collects data on severe obstetric complications and patient outcomes in order to inform quality improvement efforts in maternal care. Conditional support for rulemaking is contingent on successful completion of measure testing and NQF endorsement.

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Section 3: Public Comments

Society for Maternal-Fetal Medicine

The measure specifications were shared with the members of the Patient Safety and Quality Committee of the Society for Maternal-Fetal Medicine. Four physicians responded with these concerns:

Doctor-1 A few things…and I should preface this by saying that this is not a reaction to it based on a resistance to measuring SMM.

1. It does seem like some careful thought should be given to the name. These are sometimes complications that are not the fault of the patient or the healthcare system…they happen. Acute heart failure (cardiomyopathy of pregnancy), ruptured aortic aneurysms (for people who have undiagnosed aneurysms), amniotic fluid embolism…these are just a few examples. The reason I bring this up is because agencies like Leapfrog and USNWR will jump on this and rate hospitals against each other against this metric without actually thinking that a good number of the things in this are not measures of the quality of care. Instead of using the word complications, which generally points at mishaps and misadventures when the general public reads it, they should come up with a more nuanced term that gives a sense that these are a general set of morbidities more than anything.
2. It is an extraordinarily complicated eCQM. Is this platelet count of <100 in someone who was admitted with a normal one? Same with SCr 2 or more? Is this a ruptured aortic aneurysm or is it just the diagnosis being in a chart? Was it an indicated hysterectomy for accreta or one that happened because of atony and delayed response to PPH? In the end, a complicated eCQM like this will require a deep manual review before the data submission, which generally negates the attempt at creating a good eCQM.
3. Generally, coding for maternal medical complications is not done as thoroughly by hospitals as it is done for other conditions, for various reasons. This will be a major adjustment for hospitals. Not saying that an adjustment may not be necessary, but the group might not understand that there is a gap in this that exists right now specifically in maternal coding.
4. It is also very biased against the hospitals that get referred the most complicated patients. Platelets <100, SCr >2, hysterectomies (in accrete patients)…those patients are risked into hospitals that are rated higher levels of maternal care. If Levels of Maternal Care work, higher levels will have higher scores for the most part.

Doctor-2

A few additional... For the top bunch of criteria...some smaller hospitals use ICU for closer surveillance to have enhanced observation and we need to be careful about disincentivizing this.

ICU admissions should be triggers for review for preventability but not a quality metric in and of themselves.

We should continue to support the prior ACOG/SMFM position (Obstetric Care Consensus) that SMM alone should not be used as a quality metric for all of the reasons that Doctor-1 outlined, as well as those outlined in the original publication. Standardized triggers (ICU admission, 4 or more units transfusion) should prompt reviews for preventability.

I feel pretty strongly that transfusion of 1 unit of blood is not a severe obstetric complication and

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continues to be a main driver of SMM...think we should strongly push back on equating a unit of RBC transfusion with AFE, cardiac arrest, etc.

Doctor-3

The measure outlined represents a very slippery slope, one that I fear may lead to potential reimbursement repercussions, certification withdrawals / awards, and creation of even greater hospital inequity, etc. Although the methodology used by USNWR and other organizations like LeapFrog leave much to be desired, they by and large dont have the support of the medical community. There are many factors that play a role in a patient's decision making process about which hospital to give birth in besides rankings, and by creating a medical standard, we will in essence create a grading system for all hospitals that will have repercussions whether foreseeable or not. In addition, as the metrics stand in their current form below, they definitely favor hospitals that never deal with a complicated patient population. Although it specifies "severe obstetric complications which occur during the inpatient delivery hospitalization", it is very hard to control for a patient that presents with an accreta and receives MTP and spends time in the ICU: an accreta center would be punished, because most accretas do not "present in DIC". Similarly for those hospitals that deal with maternal cardiac lesions, bleeding disorders, etc. would be punished.

Doctor-4

Two questions that these metrics should attempt to answer. #1 do low risk patients have good outcomes at a given institution. #2 do high risk patients have lower complications at a given institution. I think these two questions should be clearly distinguished from each other and the metric for each are different.

Rationale for #1: most obstetric patients are low risk. Within a given community, low risk patients usually have numerous choices when it comes to obstetric care providers and institutions for obstetric care. The dynamic nature of community obstetric care provide some degree of random variation within regional systems to provide comparison of outcomes. In this setting, I would propose quality metric where the numerator can be SMM but the denominator should be all uncomplicated pregnancies (18-35yo first pregnancy without any medical or fetal complications). In order to minimize statistical clustering phenomenon the SMM may need to be time averaged over a periods of a couple years, especially for small volume hospitals.

Rationale for #2: high risk patients are often referred to regional referral centers. Referral centers generally have large catchment areas. As a result of the geographic limitations, population demographic characteristics tend to vary more between these referral centers, as would the complications being managed. As an example: racial/ethnic variations could mean some regions see more eclampsia, where as other regions see more HELLP, or some regions have higher diabetes or chronic hypertension etc. In my opinion, quality metrics can still be used for these institutions but rather than comparing between institutions, it should be used to identify areas of improvement and gauge efficacy of these projects. One could use various metrics, but I think a possible manageable option would be to use SMM as the numerator divided by the total of chronic hypertension and pregestational diabetes as these are the two most common medical complications and pretty much every population data collect these information, which have become more and more reliable over the years.

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Finally, I also share the same concern with that the use of some severe and rare outcomes as the numerator would not reflect the general quality of obstetric care. While some of these outcomes may be preventable, otherwise are purely random. That's why I think it's important to push for a time averaged numerator to iron those out.

2020 Mom

On behalf of 2020 Mom, we appreciate the leadership of the Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum (NQF) in advancing quality of medical care and prioritizing value-based payment, and we thank you for this comment opportunity. 2020 Mom is a national nonprofit that aims to close the gaps in maternal mental healthcare. We believe that as the nation continues to grapple with a maternal morbidity and mortality crisis, we must ensure that maternal mental health is also prioritized, as suicide and overdose are leading causes of death in the first year postpartum.

In 2019, two perinatal depression measures became available for reporting by commercial and Medicaid health insurance plans: the Prenatal Depression Screening and Follow-Up HEDIS and the Postpartum Depression Screening and Follow-Up HEDIS. We are grateful for these measures, as they will help ensure that providers screen for depression during the prenatal/postpartum period. Unfortunately, data is still not available on these quality measures. We must monitor screening and follow-up rates, per both measures, and as utilization of the measures continues, we must ensure that we can track any correlation between screening/follow-up on positive screen and receipt of treatment services/reduction in symptomatology.

While maternal mental health is not one of the measures under consideration this year, we urge CMS and NQF to maintain focus on this issue through ongoing guidance to providers on the Prenatal Depression Screening and Follow-Up HEDIS and the Postpartum Depression Screening and Follow-Up HEDIS. Additionally, where applicable, in any maternal morbidity measures, maternal mental health (i.e., perinatal depression, perinatal anxiety, perinatal obsessive-compulsive disorder, etc.) should be incorporated. For example, in MUC2021-104, which focuses on Severe Obstetric Complications, psychosis--which can onset in the immediate postpartum--should be considered.

We appreciate your ongoing commitment to maternal health, and look forward to working together on ensuring that maternal mental health measures are utilized and reported on.

Mom Congress

On behalf Mom Congress , we appreciate the leadership of the Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum (NQF) in advancing quality of medical care and prioritizing value-based payment. Mom Congress is the policy organization for moms in the U.S. – a membership organization that is addressing the most pressing policy issues of motherhood including what we call the "motherload" (the stress that U.S. mothers carry, at higher rates than other developed countries). Our top priorities are maternal mortality, maternal mental health, Black & Indigenous maternal health, and paid family leave and affordable childcare. Considering our commitment to reducing maternal deaths, we appreciate MUC2021-104, which focuses on Severe Obstetric Complications. We support the measure, as it will measure severe maternal morbidity diagnoses and severe maternal morbidity procedures.

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Federation of American Hospitals

The Federation of American Hospitals (FAH) strongly supports efforts to address pregnancy-related morbidity and mortality and we appreciate the Centers for Medicare and Medicaid Services (CMS) putting forward an outcome measure that specifically addresses this issue. On review of the materials released for public comment by CMS on November 19, 2021, it appears that an exclusion for patients diagnoses with Covid-19 is under consideration and the FAH strongly encourages CMS to add this exclusion in light of the public health emergency and to submit the measure to the National Quality Forum for endorsement.

In addition, while we encourage CMS to further test this electronic clinical quality measure (eCQM) 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, we are encouraged to see the number of hospitals and vendor systems used (based on the measure methodology report released for public comment). As a result, the FAH recommends that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

American Medical Association

The American Medical Association (AMA) remains committed to addressing inequity and decreasing maternal morbidity and mortality and we believe that this measure in addition to initiatives such as the Centers for Disease Control and Prevention (CDC) Alliance for Innovation on Maternal Health (AIM) bundles will drive improvements in maternal complications and death. Based on the materials released for public comment by the Centers for Medicare and Medicaid Services (CMS) on November 19, 2021, an exclusion for patients diagnosed with Covid-19 is under consideration and the AMA strongly encourages its addition to CMS. We also ask that the MAP and the NQF Standing Committee consider whether inclusion of some of the risk factors, specifically severe and other preeclampsia and obstetric VTE, are appropriate since their inclusion could mask potentially avoidable severe maternal morbidity. The AMA recommends that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

American College of Obstetrician Gynecologists (ACOG)

ACOG appreciates the emphasis CMS and CORE are placing on improving maternal health outcomes and preventing adverse health outcomes. The U.S. is experiencing a maternal mortality crisis and is the only developed country with a rising maternal death rate. Equally, severe maternal morbidity (SMM) is rising in the U.S. Identifying SMM is important for preventing injuries that lead to mortality and for highlighting opportunities to avoid repeat injuries. Therefore, the creation of measures around SMM, including the Severe Obstetric Complications eCQM, is critical to improving quality of care of patients.

This new measure tackles the issue of SMM by utilizing an outcome based on the Centers for Disease Control and Prevention (CDC) definition of SMM, which includes 21 indicators of SMM. Many of these indicators are commonly utilized and recognized components to identifying SMM and are reflected in the 2021 Alliance for Innovation on Maternal Health's (AIM) SMM Codes List . The current measure documentation references the 2019 AIM SMM Codes List and it is recommended to update the reference to the most current version of the AIM SMM Codes List.

ACOG has not officially endorsed or created a single, comprehensive definition of SMM. This is relevant as ACOG's 2016 Obstetric Care Consensus on Severe Maternal Morbidity: Screening and Review

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(reaffirmed in 2021) specifically indicates that transfusions of four or more units of blood should not be included as indicator of SMM as it is typically indicative of a preexisting condition not related to pregnancy.

Blood transfusions are included as an indicator of SMM as part of the numerator of this measure. While the risk adjustment component of the measure includes bleeding disorders, there should be consideration of including a specific numerator exclusion for transfusions of four or more units of blood to ensure that appropriate SMM identification is achieved without penalizing providers for non-pregnancy related disorders.

This measure has the potential to useful and meaningful to patients, especially in conjunction with the recently instituted Maternal Morbidity Structural Measure in the Inpatient Prospective Payment System (IPPS) final rule focused on the implementation of quality improvement patient safety bundles through perinatal quality collaboratives. Institutions should be striving to develop and implement measures that focus on tackling issues surrounding maternal morbidity and mortality, similar to these current efforts.

The measure specifications should be available to patients in clear language and appropriately include explanations for conditions that are captured in the measure.

America's Essential Hospitals

Current quality measures related to pregnancy and maternal health proposed for or in public reporting programs are largely process measures. Directionally, we support the introduction of measures that directly address patient outcomes. The obstetric complications measure has been tested in nine health care pilot sites comprising 27 individual hospitals, using three different electronic health record systems. As noted by the measure developer, there are considerable racial and ethnic disparities in maternal outcomes. As part of the NQF endorsement process, we support the results of this measure being stratified by race and ethnicity to better identify disparities. We applaud the inclusion of a “housing instability” variable in the risk adjustment for this measure; however, the source of this housing data is unclear as well as the consistency in which this data is collected and reported by hospitals. We encourage further examination of social risk factors beyond housing that can be incorporated into the risk adjustment for this measure (e.g., food insecurity).

American Hospital Association

The AHA agrees with the MAP’s recommendation of Conditional Support for this measure, with the conditions being completed testing and NQF endorsement. Maternal health is a priority for the AHA and its member hospitals and health systems; a commitment to women’s health, healthy pregnancy and a good start for all children is a cornerstone to improving the nation’s health. We support the general concept and direction of this measure; we believe that concerns that we have regarding the complexity of the measure’s specifications are likely to be addressed during testing and the NQF review process.

As the agency and its contractors acknowledge in the methodology report, there is a dearth of available outcomes-based quality measures for maternal health. The measures currently used in CMS and similar quality reporting and assessment programs evaluate perinatal processes (exclusive breast milk feeding, PC-05), attestation to involvement in perinatal quality improvement programs (maternal morbidity structural measure), or intermediate outcomes (elective delivery, PC-01). Even in Medicaid and the Children’s Health Insurance Program there are only 11 voluntarily reported measures related to maternal and perinatal health, and none specifically address maternal morbidity. This measure would

thus fill a critical gap.

In addition, the measure's use of structured clinical data fields from certified EHR technology suggests improved accuracy over measures that are informed only by information on claims. These patient-level clinical data are vital to risk adjustment in order to identify precisely what providers can do to prevent obstetric complications. We are heartened by the progress made through the Alpha and first Beta phase of testing, in which the developers evaluated the data elements for feasibility and availability and removed elements that were not able to be captured accurately.

We do have a few concerns and questions that we recommend the measure steward and NQF committees consider as this measure progresses through the review process. First is that the numerator is extremely broad; we worry that this would put hospitals caring for more complex patients at a disadvantage. The risk adjustment methodology must be robust to account for differences in case mix. Another statistical issue is related to the numerator: while instances of severe complications are a valuable outcome to track for both providers and parents, they are still very rare. In the methodology report, the measure developers note that the low rate of occurrences may necessitate a substantial sample size. This sample size may rule out many hospitals with lower volumes.

We also urge the measure developers and NQF committees to thoughtfully evaluate the diagnoses and procedures included in the numerator to ensure that the measure focuses on preventable complications. For example, an ICU stay is not necessarily indicative of a preventable complication but rather may be the decision of a physician who wants to monitor a mother.

Finally, we appreciate the thoughtful approach to addressing the interplay of patient-level characteristics with outcomes. Social determinants of health often play a major role in how patients fare, especially mothers; we want to ensure that those drivers are not ignored or explained away, but we also need to focus quality measures used in CMS programs on issues that are within the control of the provider. In this measure, the steward would account for differences in social risk by including a housing instability variable in the risk adjustment methodology. We urge the developer to conduct additional analysis to ensure that important information regarding social determinants of health is sufficiently captured by this code, and that the code is consistently and reliably recorded so that this eCQM is truly informed by precise clinical and patient-level data.

We recognize the difficulty of developing measures for maternal health. The patient population is not homogenous, and outcomes are influenced by a complex web of factors. We appreciate the efforts in which CMS and its contractors have engaged, and are hopeful that the agency can identify measures that accurately and meaningfully contribute to improving the quality of care for mothers and babies.

American Society of Anesthesiologists

In December 2021, ASA submitted comments to CMS, Yale-CORE, and The Joint Commission on this measure. Below are excerpts from our letter that demonstrate our concern with how the measure is specified. We ask that CMS, prior to rulemaking, work with Yale-CORE and the Joint Commission to address our concerns with this measure.

Obstetric patients have benefited from the safe, effective, and patient-centered care that anesthesiologists offer each day. We identified several considerations that we hope will re-shape the measure to better meet this measure's objectives. As examples, small sample sizes for outcomes like

mortality, although very important, can easily mask a hospital's overall performance. In addition, we believe several listed complications will need to be better defined before they can be reported and used as effective measures reflective of quality care.

Anesthesiologists, other physicians, and clinicians would be able to capture the comorbidities, demographics, and other patient-level features within this measure. We recognize that maternal mortality may be challenging to track since current standards measure maternal mortality on an annual basis. We requested the measure developer reconsider specifics within "anesthesia-related complications," as they cover a wide range of severity. Further clarity on how these complications are defined in the measure may be required to know the availability of this data in routine workflows.

There are many comorbidities, whether preexisting or developed over the course of pregnancy/labor, that contribute to severe obstetric complications without any proven preventative strategies or interventions. These conditions include peripartum cardiomyopathy, amniotic fluid embolism, and disseminated intravascular coagulopathy. While data on these conditions could be useful to clinicians over time as effective treatments are developed, disease-specific data on the treatable conditions most closely correlated with maternal mortality and morbidity will be the most pertinent information to improve near-term care quality.

For the measure developer, we identified a few additional conditions categorized as "severe morbidities" that should be excluded from the measure or excluded in certain circumstances:

• Aortic aneurysm: This outcome is unrelated to obstetric care and should be excluded from the measure.

• Cardiac arrest: During obstetric care, one possible cause of cardiac arrest is an amniotic fluid embolism, which is not a preventable condition. We recommend cardiac arrest cases be excluded from the measure.

• Eclampsia: Patients are often diagnosed with eclampsia upon arrival to the hospital or soon afterward. Patients diagnosed with eclampsia should be excluded from the measure.

• Sickle cell anemia with crisis: Although physicians and other clinicians use monitoring and prevention strategies for obstetric patients with sickle cell anemia, sickle cell anemia is not necessarily an obstetric complication.

• Blood transfusion: Physicians, other clinicians, and their facilities should not be penalized or discouraged from using blood transfusion when appropriate and necessary.

• Ventilation: We are unclear how ventilation is defined in the measure. We suggest this feature of the measure could be covered under a broader complication label of "respiratory failure."

Association of American Medical Colleges (AAMC)

The AAMC agrees with the MAP's initial recommendation. Currently the CMS hospital quality programs

do not include any direct measures of maternal morbidity and obstetric complications, a priority area for quality improvement. We agree that this newly developed measure should be tested further to assess feasibility of reporting across electronic health record platforms and be NQF-endorsed as valid and reliable. Additionally, the AAMC is pleased to see this measure includes health-related social need in risk adjustment – which we believe is critical information to better understand which social needs impact outcomes to drive social investments and interventions. Relatedly, we ask that the endorsement review strongly evaluate clinical risk adjustment to ensure that this measure is not biased against hospitals that serve as regional referral centers for patients at high risk for complications. For example, hospitals that are recognized as Accreta Centers of Excellence are likely to treat patients with accretas, which may not be coded as present on admission. Finally, we agree that attention should be paid to potential unintended consequences with the measure, especially in measuring ICU admissions as a severe complication when such practice might be for closer surveillance to prevent severe complications.

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Hospital Value-Based Purchasing (VBP) Program

MUC2021-118 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Value-Based Purchasing Program, Hospital Inpatient Quality Reporting (IQR) Program

Workgroup
Hospital

Measure Description
The measure estimates a hospital-level risk-standardized complication rate (RSCR) associated with elective primary THA and/or TKA. The outcome (complication) is defined as any one of the specified complications occurring from the date of index admission to 90 days post-date of the index admission (the admission included in the measure cohort).

Numerator
The outcome for this measure is any complication occurring during the index admission [not coded present on admission (POA)] to 90 days post-date of the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable time period, the complication outcome for that patient is counted in the measure as a "yes."

We are updating this measure to include 26 additional clinically vetted mechanical complication ICD-10 codes.

Numerator Exceptions
N/A

Denominator
The target population for the publicly reported measure includes admissions for Medicare FFS beneficiaries who are at least 65 years, undergoing elective primary THA and/or TKA procedures.

The measure cohort includes admissions to non-federal, short-stay, acute-care hospitals for Medicare FFS patients aged 65 years and older with a qualifying THA/TKA procedure, not transferred in from another facility. To be included in the measure cohort used in public reporting, patients must meet the following additional inclusion criteria:

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1. Enrolled in Medicare fee-for-service (FFS) Part A and Part B for the 12 months prior to the date of admission; and enrolled in Part A during the index admission;
2. Aged 65 or older
3. Having a qualifying elective primary THA/TKA procedure; elective primary THA/TKA procedures are defined as those procedures without any of the following:

- Fracture of the pelvis or lower limbs coded in the principal or secondary discharge diagnosis fields on the index admission claim (Note: Periprosthetic fractures must be additionally coded as present on admission [POA] in order to disqualify a THA/TKA from cohort inclusion, unless exempt from POA reporting.);
- A concurrent partial hip or knee arthroplasty procedure;
- A concurrent revision, resurfacing, or implanted device/prosthesis removal procedure;
- Mechanical complication coded in the principal discharge diagnosis field on the index admission claim;
- Malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim; or,
- Transfer from another acute care facility for the THA/TKA.
- Patients are eligible for inclusion in the denominator if they had an elective primary THA and/or a TKA AND had continuous enrollment in Part A and Part B Medicare fee-for-service (FFS) 12 months prior to the date of index admission.

Denominator Exclusions

The hip/knee complication measure excludes index admissions for patients:

1. Without at least 90 days post-discharge enrollment in Medicare FFS;
2. Discharged against medical advice (AMA); or,
3. Who had more than two THA/TKA procedure codes during the index hospitalization.

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

This measure is fully developed. We are bringing an updated version of this measure back to the MAP at this time due to the addition of 26 mechanical complication ICD-10 codes, a change that was clinically vetted.

The measure underwent reliability and validity testing at the facility-level during NQF endorsement maintenance in 2020; that version of the measure does not include these additional codes. All results provided in this row are from the prior version of the measure, however we do not anticipate any problems with reliability or validity with the addition of the new codes.

Implemented version of measure: Measure Score Reliability

We estimated the overall measure score reliability by calculating the intra-class correlation coefficient (ICC) using a split sample (in other words, test-retest) method.

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Split Sample Reliability: As a metric of agreement, we calculated the ICC for hospitals with 25 admissions or more. Using the Spearman-Brown prediction formula, the agreement between the two independent assessments of the RSCR for each hospital was 0.524, demonstrating moderate reliability.

Facility-level Reliability

Signal to noise: Using the approach used by Adams et. al. and Yu et al., we obtained the median signal-to-noise reliability score of 0.87, which demonstrates “almost perfect” agreement.
We assessed measure score validity by comparing hospitals’ overall Star Rating with their RSCRs/ We predicted the THA/TKA complication measure scores would have a small association with the overall hospital star rating scores, with lower RSCRs associated with better Star ratings. Results: The correlation between THA/TKA complications and Star-Rating summary score is -0.185, which suggests that hospitals with lower THA/TKA RSCRs are more likely to have higher Star-Rating summary scores especially at the extremes.

We also assessed validity of the measure by examining the relationship between volume and the measure score for hospitals. We expect scores to be correlated with case volume at the hospital level. Results: There is a general trend that high volume hospitals (those in the upper deciles) have lower RSCRs than hospitals in other volume deciles.

Measure Score Validity: Validity Indicated by Established Measure Development Guidelines
We developed this measure in consultation with national guidelines for publicly reported outcomes measures, with outside experts, and with the public. The measure is consistent with the technical approach to outcomes measurement set forth in NQF guidance for outcomes measures, CMS Measure Management System (MMS) guidance, and the guidance articulated in the American Heart Association scientific statement, “Standards for Statistical Models Used for Public Reporting of Health Outcomes” (Krumholz, Brindis, et al. 2006; NQF 2010).

Data Element Validity: Validity of Claims-Based Measures
Our team has demonstrated for a number of prior measures the validity of claims-based measures for profiling hospitals by comparing either the measure results or individual data elements against medical records. CMS validated the six NQF-endorsed, claim-based measures currently in public reporting (AMI, heart failure, and pneumonia mortality and readmission) with models that used medical record-abstracted data for risk adjustment. Specifically, claims model validation was conducted by building comparable models using abstracted medical record data for risk adjustment for heart failure patients (National Heart Failure data), AMI patients (Cooperative Cardiovascular Project data) and pneumonia patients (National Pneumonia Project dataset). When both models were applied to the same patient population, the hospital risk-standardized rates estimated using the claims-based risk-adjustment models had a high level of agreement with the results based on the medical record model, thus supporting the use of the claims-based models for public reporting. Our group has reported these findings in the peer-reviewed literature (Krumholz et al. 2006; Krumholz et al. 2011; Krumholz et al. 2006a; Keenan et al. 2008; Bratzler 2011; Lindenauer 2011).

Validity was also assessed by the TEP. The TEP supported the final measure.

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Measure validity is also ensured through the processes employed during development, including regular expert and clinical input, and modeling methodologies with demonstrated validity in claims-based measures.

What is the target population of the measure?
The target population includes Medicare fee-for-service (FFS) patients aged 65 years or older undergoing THA/TKA.

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Orthopedic surgery

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Enrollment Data; Claims Data

If applicable, specify the data source
N/A

If EHR 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 one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
0844

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Endorsed

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NQF ID Number
NQF # 1550

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Numerator

If not exactly as endorsed, describe the nature of the differences
The measure was updated to include 26 new codes for mechanical complications:
M96.65 Fracture of pelvis following insertion of orthopedic implant, joint prosthesis, or bone plate
M96.661 Fracture of femur following insertion of orthopedic implant, joint

If endorsed: Year of most recent CDP endorsement
2021

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
This measure is currently in use in the HVBP program. The measure has now been updated for this MUC submission: 26 codes were added to the mechanical complications definition. These clinically relevant changes contributed to an increase of ~0.5% (from 2.42% to 2.93%) in the THA/TKA national observed complication rate for 2021 reporting period. We are bringing this updated measure back to the MAP. No other changes to the measure have been made.

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
Year: 2011-2012, 2012-2013
Measure Id: MUC20, MUC523
Workgroups: Hospital, 2012
Programs: Hospital Inpatient Quality Reporting, 2011, Hospital Value Based Purchasing, 2012
Recommendation: February 2012 report, IQR: Support; 2013 report, HVBP: Support
Report Page Number: 2012 report: page 78; 2013 report: page 134

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs
Inpatient Quality Reporting (2015 – scheduled removal 2023 reporting year) Hospital Value Based Purchasing (implemented FY2019 with FY 2021 first reporting year)

What other federal programs are currently using this measure?
Hospital Inpatient Quality Reporting Program ;Hospital Value-Based Purchasing Program

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
1. Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode of Care for THA/TKA;
2. Hospital-level 30-Day All-Cause Risk-Standardized Readmission Rate Following Elective Primary Total Hip Arthroplasty (THA) And/Or Total Knee Arthroplasty (TKA)

How will this measure be distinguished from other similar and/or competing measures?
No other measure in Hospital IQR or VBP assess complications following primary elective THA/TKA. The measure is complementary to and harmonized with the payment and readmission measures in row 105.

How will this measure add value to the CMS program?
No other measure in Hospital IQR or VBP assess complications following primary elective THA/TKA. The measure is complementary to and harmonized with the payment and readmission measures in row 105. The original version of the measure is currently in use in VBP. Complications are an important outcome for these very common elective procedures.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

See Evidence Attachment

Evidence that the measure can be operationalized

The current version of the measure has already been operationalized. CMS uses the measure in the Hospital VBP program and publicly reports the measure on Care Compare.

The measure was developed using claims data from seven standard analytic files contained in the Chronic Condition Warehouse (CCW) data. The CCW data are derived from the Medicare claims in the Standard Analytic Files. The CCW data contain data from the Medicare FFS institutional and non-institutional claims, enrollment and eligibility information, and assessment data for up to 100% of the Medicare FFS beneficiary population for particular conditions and procedures. The data are organized by predefined chronic conditions, but can also be used to define individualized patient cohorts, as described below. The annual CCW datasets include claims data from all seven standard files (inpatient, skilled nursing facility, outpatient, home health agency, hospice, carrier, and durable medical equipment) that can be linked across care settings, services, supplies, and years using a unique patient identifier. Specific information available in the CCW data includes diagnosis codes, procedure codes, quantity/units of services used, and payments made by CMS, patients, and other insurers to providers.

How is the measure expected to be reported to the program?

Claims

Feasibility of Data Elements

ALL data elements are in defined fields in administrative claims

Evidence of Performance Gap

Variation in complication rates indicates opportunity for improvement. We conducted analyses using data from April 1, 2016 to March 31, 2019 Medicare administrative claims data (n= 962,744 admissions from 3,418 hospitals).

The three-year hospital-level risk standardized complication rate (RSCR) has a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate is 2.4%.

Distribution of Hospital THA/TKA RSCRs over Different Time Periods

Results for each data year

Characteristic//04/2016-03/2017//04/2017-03/2018//04/2018-03/2019//04/2016-03/2019

Number of Hospitals//3274//3271//3250//3418

Number of Admissions//336445//330765//295534//962744

Mean (SD)//2.6(0.4)//2.4(0.4)//2.3(0.3)//2.5(0.5)

Range (Min-Max)//1.1-9.3//1.3-13//1.2-4.5//1.2-10.6

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Minimum//1.1//1.3//1.2//1.2

10th percentile//2.1//2.1//2.0//1.9

20th percentile//2.3//2.2//2.1//2.1

30th percentile//2.4//2.3//2.2//2.3

40th percentile//2.5//2.3//2.2//2.3

50th percentile//2.5//2.4//2.3//2.4

60th percentile//2.5//2.4//2.3//2.5

70th percentile//2.7//2.5//2.4//2.6

80th percentile//2.8//2.7//2.5//2.8

90th percentile//3.0//2.9//2.7//3.0

Maximum//9.3//13.0//4.5//10.6

Unintended Consequences

We did not identify any unintended consequences during measure development and testing. We are committed to monitoring this measure's use and assessing potential unintended consequences over time, such as the inappropriate shifting of care or coding/billing practices, increased patient morbidity and mortality, and other negative unintended consequences for patients.

Outline the clinical guidelines supporting this measure

N/A

Were the guidelines graded?

N/A

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure:

Unable to determine

Estimate of Annual Denominator Size

N/A

Estimate of Annual Improvement in Measure Score

N/A

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Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure
N/A

Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
During 3 TEP meetings throughout development, including during outcome and cohort development, model building, and risk adjustment methodology

Total Number of Patients and/or Caregivers Consulted
1

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:11

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
1

Burden for Patient: Does the measure require survey data from the patient?
No

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If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Working groups; Standard TEP

Total Number of Clinicians/Providers Consulted
16

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
16

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
Split sample: Agreement between the two independent assessments of the RSCR for each hospital was 0.524 (moderate reliability)

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Signal-to-noise: median 0.87 (ranging from 0.46 to 1.00) which, according to the conventional interpretation, is “almost perfect” (Shrout et al. 1979).

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise; ICC (Intraclass correlation coefficient); Test-Retest

Reliability Testing Sample Size
As noted above, testing was conducted on the currently implemented version of the measure, not the updated version with the addition of 26 complication codes. We present these testing details and results below. The number of measured entities with at least one admission in the cohort was 3,418. The results of the reliability testing was conducted for hospitals with at least 25 cases which included 2,763 hospitals. The 25 cases threshold was used to align with how the measure is publicly reported.

Reliability Testing Statistical Result
Split sample: Agreement between the two independent assessments of the RSCR for each hospital was 0.524 (moderate reliability)
Signal-to-noise: median 0.87 (ranging from 0.46 to 1.00) which, according to the conventional interpretation, is “almost perfect” (Shrout et al. 1979).

References
Landis J, Koch G. The measurement of observer agreement for categorical data. Biometrics. 1977; 33:159-174.

Shrout P, Fleiss J. Intraclass correlations: uses in assessing rater reliability. Psychological Bulletin. 1979; 86:3420-3428.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
25, 80.8%

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity

Validity Testing Sample Size
3418

Validity Testing Statistical Result
We assessed measure score validity by comparing hospitals’ overall Star Rating with their RSCRs/ We predicted the THA/TKA complication measure scores would have a small association with the overall hospital star rating scores, with lower RSCRs associated with better Star ratings. Results: The correlation

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between THA/TKA complications and Star-Rating summary score is -0.185, which suggests that hospitals with lower THA/TKA RSCRs are more likely to have higher Star-Rating summary scores especially at the extremes.

We also assessed validity of the measure by examining the relationship between volume and the measure score for hospitals. We expect scores to be correlated with case volume at the hospital level. Results: There is a general trend that high volume hospitals (those in the upper deciles) have lower RSCRs than hospitals in other volume deciles.

Validity Testing Interpretation of Results

Results demonstrate an observed trend of lower risk-standardized complications with higher star ratings, especially at the extremes, which supports measure score validity. Additionally, this validation approach compared various categories and deciles of hospital THA/TKA admission volume with THA/TKA complication measure scores– these results demonstrate an observed trend of higher hospital volume with lower complication measure scores. Overall, the results above show that the trend and direction of this association is in line with what would be expected.

The TEP also assessed the overall face validity of the measure score as specified. Measure validity is also ensured through the processes employed during development, including regular expert and clinical input, and modeling methodologies with demonstrated validity in claims-based measures.

Measure performance – Type of Score

Ratio

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

Variation in complication rates indicates opportunity for improvement. In 2019 (current version of the measure) we conducted analyses using data from April 1, 2016 to March 31, 2019 Medicare administrative claims data (n= 962,744 admissions from 3,418 hospitals). The three-year hospital-level risk standardized complication rate (RSCR) has a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate is 2.4%.

For the updated version of the measure for this MUC submission, 26 codes were added to the mechanical complications definition. These clinically relevant changes contributed to an increase of ~0.5% (from 2.42% to 2.93%) in the THA/TKA national observed complication rate for 2021 reporting period.

Benchmark, if applicable

N/A

Measure Contact Information

Measure Steward

Centers for Medicare & Medicaid Services

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Measure Steward Contact Information
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Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-118 Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA)

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure continues to address a key Healthcare Quality Domain and CMS Meaningful Measure priority area of Safety. This is the only measure within the HVBP that evaluates the complication rates following elective THA and/or TKA. A prior version of this measure has been evaluated and supported by the MAP for HVBP in 2013 and has been updated to include 26 codes to the mechanical complication's definition. The developer notes that these clinically relevant changes contributed to an increase of ~0.5% (from 2.42% to 2.93%) in the THA/TKA national observed complication rate for 2021 reporting period.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is an outcome measure that captures complications of Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA). Variation in complication rates across hospitals indicates there is room for quality improvement and targeted efforts to reduce these

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complications can result in better patient care and potential cost savings (Navathe et al, 2017; Cyriac et al., 2016; Borza et al., 2019).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: As of 2010, there were over 370,000 THAs and 600,000 TKAs performed annually. Of these procedures, complications related to anesthesia, comorbidities, and allergic reactions pose a significant quality challenge (Martin et al., 2020; Erens et al., 2021). During a prior NQF endorsement review, the developers provided three-year, hospital-level, risk standardized complication rates (RSCR) from April 1, 2016 to March 31, 2019 using Medicare administrative claims data (n= 962,744 admissions). The RSCRs had a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate was 2.4%. These data demonstrate a range of performance and opportunities for improvement.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital settings. This measure was previously submitted for endorsement review in 2021 and has been updated since the last evaluation. The developer plans to resubmit with updated specifications for endorsement review by the NQF Patient Safety Standing Committee in the Consensus Development Process (CDP). A prior version of this measure has been in use in the Inpatient Quality Reporting (2015 – scheduled removal 2023 reporting year) and the Hospital Value Based Purchasing (implemented FY2019 with FY 2021 first reporting year).

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The measure is fully specified and uses administrative claims data and enrollment data and as such, it offers no data collection burden to hospitals or providers. During the prior NQF endorsement review of this measure the Standing Committee had no concerns regarding the feasibility of the measure. The expanded 26 codes for mechanical complication's definition do not pose a feasibility challenge.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: No

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital settings. The expanded 26 codes for mechanical complication's definition should be reviewed by the relevant NQF standing committee to confirm validity.

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?
Yes/No: No

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Justification and Notes: No unintended consequences or implementation challenges have been identified. The developer reports this measure is currently in use in the Hospital Value-Based Purchasing Program and Hospital Inpatient Quality Reporting Program, however, the CMS Measures Inventory Tool (CMIT) lists the measure as inactive under the Hospital IQR Program with an end date of reporting as 1-1-2021 and is scheduled for removal 10-1-2022.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- No issues or concerns

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 votes
2 – 0 votes
3 – 1 votes
4 – 7 votes
5 – 2 votes

MAP Health Equity Advisory Group Input:

The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity

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Average: 2.9
1 – 0 votes
2 – 7 votes
3 – 3 votes
4 – 6 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional support for rulemaking

Summary: What is the potential value to the program measure set?
This fully developed and specified measure addresses a critical and preventable safety event in the Hospital Value-based Purchasing Program (HVBP). The measure is currently in use and has been expanded to include 26 codes to the mechanical complication's definition. The measure is otherwise identical to the existing measure in HVBP.

Summary: What is the potential impact of this measure on quality of care for patients?
As of 2010, there were over 370,000 THAs and 600,000 TKAs performed annually. Of these procedures, complications for patients related to anesthesia, comorbidities, and allergic reactions pose a significant quality challenge. During NQF endorsement review, the developers provided three-year, hospital-level, risk standardized complication rates (RSCR) from April 1, 2016 to March 31, 2019 using Medicare administrative claims data (n= 962,744 admissions). The RSCRs had a mean of 2.5% and range from 1.2-10.6% in the study cohort. The median risk-standardized rate was 2.4%. These data demonstrate a wide range of performance and opportunities for improvement in patient care. Conditional Support for Rulemaking is recommended pending NQF Standing Committee review of the 26 codes added to the mechanical complication's definition.

Section 3: Public Comments

Federation of American Hospitals
The Federation of American Hospitals (FAH) appreciates the inclusion of the additional ICD-10 codes for mechanical complications in response to feedback from subject matter experts. While we agree that these changes will likely not significantly impact the reliability and validity of the measure, we encourage the Centers for Medicare and Medicaid Services to update the testing and achieve endorsement of these changes the National Quality Forum before implementation in any quality program. As a result, the FAH requests that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

American Medical Association
The American Medical Association recommends that the Centers for Medicare and Medicaid Services

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(CMS) reconsider the addition of the ICD-10 codes for mechanical complications if the National Quality Forum Standing Committee does not agree and continue to monitor whether their addition impacts the reliability and validity of the measure.

Premier, Inc.
Premier conditionally supports adoption of this refined measure. CMS should seek endorsement before moving forward with the measure.

Johnson & Johnson
Johnson & Johnson supports the recommendation of the workgroup to conditionally move forward with support for rulemaking, pending the NQF Standing Committee review of the 26 codes to the mechanical complication's definition. Johnson & Johnson supports meaningful patient-centered care planning measures that promote reductions in treatment-related complications. We further agree with the development of patient-reported outcome performance measures that close gaps in CMS priority measure development areas.

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MUC2021-131 Medicare Spending Per Beneficiary (MSPB) Hospital

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Hospital Value-Based Purchasing Program, Hospital Inpatient Quality Reporting Program

Workgroup
Hospital

Measure Description
The measure evaluates hospitals' efficiency relative to the efficiency of the national median hospital and assesses the cost to Medicare for Part A and Part B services performed by hospitals and other healthcare providers during an MSPB Hospital episode, which is comprised of the periods 3-days prior to, during, and 30-days following a patient's hospital stay. The measure is not condition specific and uses standardized prices when measuring costs. Eligible beneficiary populations include beneficiaries enrolled in Medicare Parts A and B who were discharged between January 1 and December 1 in a calendar year from short-term acute hospitals paid under the Inpatient Prospective Payment System.

Numerator
The numerator of the MSPB Hospital measure is the hospital's average risk-adjusted episode cost, also referred to as the MSPB Amount. The MSPB Amount is calculated as the average ratio of Medicare Part A and Part B standardized episode costs to predicted episode costs from all episodes at the hospital, multiplied by the average standardized episode cost nationwide.

Numerator Exceptions
The following episode-level exclusions apply to all episodes triggered at a particular hospital:

1. The beneficiary has a primary payer other than Medicare for any time during the episode window or 90-day lookback period prior to the episode start day
2. The beneficiary was not enrolled in Medicare Parts A and B for the entirety of the lookback period plus episode window, or was enrolled in Part C for any part of the lookback plus episode window
3. The beneficiary's date of birth is missing
4. The beneficiary's death date occurred before the episode ended
5. The index admission for the episode did not occur in a subsection (d) hospital paid under the IPPS or occurred in an acute hospital in Maryland
6. The discharge of the inpatient stay occurred in the last 30 days of the
7. measurement period
8. The index admission for the episode was involved in an acute-to-acute hospital transfer
9. The inpatient claim of the inpatient stay indicated a $0 actual payment or a $0 standardized payment.

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Denominator
The denominator of the MSPB Hospital measure is the episode-weighted median MSPB Amount across all episodes nationally.

Denominator Exclusions
The following episode-level exclusions apply to episodes triggered at all eligible hospitals in the nation:

1. The beneficiary has a primary payer other than Medicare for any time during the episode window or 90-day lookback period prior to the episode start day
2. The beneficiary was not enrolled in Medicare Parts A and B for the entirety of the lookback period plus episode window, or was enrolled in Part C for any part of the lookback plus episode window
3. The beneficiary's date of birth is missing
4. The beneficiary's death date occurred before the episode ended
5. The index admission for the episode did not occur in a subsection (d) hospital paid under the IPPS or occurred in an acute hospital in Maryland
6. The discharge of the inpatient stay occurred in the last 30 days of the
7. measurement period
8. The index admission for the episode was involved in an acute-to-acute hospital transfer
9. The inpatient claim of the inpatient stay indicated a $0 actual payment or a $0 standardized payment.

Denominator Exceptions
N/A

State of development
Fully Developed

State of Development Details
The measure underwent extensive testing prior to the NQF endorsement submission in August, 2020. Specifically, the following testing was conducted: reliability, validity, exclusions, evidence-based risk-adjustment strategy, performance gap, and missing data. For reliability and validity testing results, please refer to the "Reliability Testing" and "Validity Testing" subsections of this form.

What is the target population of the measure?
Medicare Fee for Service

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Other: N/A

Measure Type
Efficiency

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Claims Data

If applicable, specify the data source
N/A

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If EHR 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 one healthcare domain applies to this measure?
Affordability and Efficiency

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
2751

Alternate Measure ID
MSPB 1

What is the endorsement status of the measure?
Endorsed

NQF ID Number
NQF # 2158

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
No

If not exactly as endorsed, specify the locations of the differences
Target Population; Other: See next field

If not exactly as endorsed, describe the nature of the differences
The current version of the MSPB Hospital measure is NQF endorsed (NQF ID #2158). The revised version of the measure is currently undergoing NQF endorsement, and is expected to receive its endorsement status in the summer of 2021.

Refinement 1: In the current MSPB Hospital measure, inpatient readmissions occurring in the 30-day post-discharge period of an episode cannot initiate (or trigger) a new episode. The methodology was refined to allow readmissions to trigger a new episode and include an indicator variable in the risk adjustment model to account for the differences in expected costs for episodes that are readmissions. Allowing readmissions to trigger new episodes (i) increases the number of episodes for which a provider can be scored and aligns the incentives of the cost measure during readmissions; and (ii) captures potentially high-cost services that are otherwise excluded. By allowing readmission inpatient stays to trigger new episodes in the MSPB Hospital measure, the number of episodes used in MSPB Hospital measure score calculations increased by 16.97 percent from 5.10 million to 5.97 million episodes. Further, the inclusion of an indicator variable to control for the readmission characteristic of an episode controlled for the higher observed cost of readmission-based episodes (mean: $26,552) relative to non-readmission episodes (mean: $21,565), as evidenced by average observed to expected episode cost ratios that are close to 1.00 and by differences between these average observed to expected episode cost ratios for readmission and non-readmission episode types that were largely less than 1 percent. Taken with the change in measure risk adjustment calculation that ensures equal weight of each risk-

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adjusted episode at a hospital, the MSPB Hospital measure refinements resulted in score changes of less than 3 percent, relative to the original measure methodology, for approximately 94.5 percent of providers. Refinement 2: One step of the current MSPB Hospital methodology calculates the measure score as the sum of total observed costs divided by the sum of total expected costs across all episodes attributed to a hospital. The refinement of this step changes the calculation to the average episode's ratio of observed costs divided by expected costs across the population of attributed episodes for a hospital. Specifically: • Current methodology to calculate the MSPB Amount: ((Sum of Observed Costs//# of Attributed Episodes) / (Sum of Expected Costs/# of Attributed Episodes)) * Average Observed Cost Nationally • Revised methodology to calculated the MSPB Amount: (Sum (Observed Costs/Expected Costs) / /# of Attributed Episodes) * Average Observed Cost Nationally Changing the measure calculation (i) slightly increases measure reliability with minimal score changes; and (ii) evenly weights attributed episodes in the final performance score, where previously good or poor performance on more expensive episodes could have more weight in the final provider's score. The overall impact of this refinement on measure scores was generally limited (e.g., less than 3 percent change in the overall score distribution end points), while allowing each risk-adjusted episode equal weight in a provider's measure score.

If endorsed: Year of most recent CDP endorsement
2017

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
None

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

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Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
2011, 2012
2011: MUC41 , 2012: 1643
MAP Hospital Workgroup
2012 MAP: HVBP and HIQR
2013 MAP: HVBP and HIQR
Recommendation: 2012 MAP: Hospital VBP and Hospital IQR
MAP's recommendation: Support
2013 MAP: Hospital VBP and Hospital IQR;
MAP's recommendation: Support
Input on Measures Under Consideration by HHS for 2012 Rulemaking, Final Report (February, 2012): MAP reviewed the MSPB Hospital measure for the following programs: Hospital IQR; Hospital VBP; Long-Term Care Hospital Quality Reporting (LTCHQR); and PPS-Exempt Cancer Hospital Quality Reporting (PCHQR)
MAP recommendations: "Though measures of cost have been identified as a high-priority gap area, MAP could not support the inclusion of the Medicare Spending per Beneficiary measure at this time. However, MAP strongly supports the direction of this measure pending additional specification and testing. MAP encourages harmonization with the similar measure concept under consideration within the Physician Value-Based Payment Modifier program."

Support Direction. Support measure concept but need specifications."
Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report (February, 2013): MAP reviewed the MSPB Hospital measure for the following programs: Hospital IQR, Value-Based Payment Modifier Program, and Hospital VBP.
MAP Recommendations: "MAP supported the Medicare Spending per Beneficiary measure, noting the statutory requirement for this measure and that this measure is expected to be submitted for NQF-endorsement this year", and "Support: Addresses specific program attributes. Addresses an NQS priority not adequately addressed in the program measure set".
Input on Measures Under Consideration by HHS for 2012 Rulemaking, Final Report (February, 2012): Pages 83 and 84
MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, Final Report (February, 2013): Pages 30 and 136.

What is the history or background for including this measure on the new measures under consideration list?
Measure currently used in a CMS program, but the measure is undergoing substantial change

Range of years this measure has been used by CMS Programs
Hospital Value-Based Purchasing (FY2015 – present), Hospital Inpatient Quality Reporting (FY2014 – FY2019).

What other federal programs are currently using this measure?
Hospital Value-Based Purchasing Program

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Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
Sec. 1886 (o) (2) (B) (ii) of the Social Security Act.

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
In the United States, healthcare costs consume an ever-increasing amount of our nation's resources. One source of these rising healthcare costs is payment systems that reward medical inputs rather than outcomes. Medicare is transforming from a system that rewards volume of service to one that rewards efficient, effective care and reduces delivery system fragmentation. To advance this transformation, the Centers for Medicare & Medicaid Services (CMS) provides financial incentives to hospitals based on their performance on selected quality measures. These measures include evaluations of hospitals' clinical process of care, patient perspective of care, outcomes, and efficiency. By measuring Medicare spending through the MSPB Hospital measure, CMS aims to reward hospitals that can provide efficient care at a lower cost to Medicare.

The MSPB Hospital measure evaluates hospitals' risk-adjusted episode costs relative to the risk-adjusted episode costs of the national median hospital. This scoring allows hospitals to improve their score by spending less than the episode-weighted risk-adjusted median cost during a given performance period through improved care coordination and provision of efficient care. For instance, hospitals can decrease (i.e., improve) their risk-adjusted episode costs through actions such as: 1) improving coordination with post-acute providers to reduce the likelihood post-discharge of adverse events, 2) identifying unnecessary or low-value post-acute services and reducing or eliminating these services, or 3) shifting post-acute care from more expensive services (e.g., skilled nursing facilities) to less expensive services (e.g., home health) in cases that would not affect patient outcomes. Care coordination helps ensure a patient's needs and preferences for care are understood, and that those needs and references are shared between providers, patients, and families as a patient moves from one healthcare setting to another. People with chronic conditions, such as diabetes and hypertension, often receive care in multiple settings from numerous providers. As a result, care coordination among different providers is required to avoid waste, over-, under-, or misuse of prescribed medications and conflicting plans of care.

Evidence that the measure can be operationalized
This is a claims-based measure and will not require any additional submission of data.

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How is the measure expected to be reported to the program?
Claims

Feasibility of Data Elements
ALL data elements are in defined fields in administrative claims

Evidence of Performance Gap
Analysis of all IPPS eligible hospitals with at least 25 episodes for the 2018 performance period shows a large range of provider scores on the MSPB Hospital measure. The MSPB Hospital measure score has the following distributional characteristics:

- Mean: 0.99, standard deviation: 0.08
- Median: 0.99
- Min: 0.49, max: 1.68
- Interquartile range spans from 0.94 to 1.03

The score decile distribution for the 2018 performance period is:

- 10th: 0.90
- 20th: 0.93
- 30th: 0.95
- 40th: 0.97
- 50th: 0.99
- 60th: 1.01
- 70th: 1.02
- 80th: 1.05
- 90th: 1.08

Analysis of MSPB Hospital measure score changes between 2017 and 2018 showed that hospital scores do vary over time, as 48.8 percent of providers evidenced improved (lower) scores. The distribution in score change between these two years, with negative values indicating improvement, is as follows:

- Min: -166.24%
- 5th: -17.54%
- 10th: -4.15%
- 25th: -1.76%
- 50th: 0.10%
- 75th: 2.01%
- 90th: 4.41%
- 95th: 18.92%
- Max: 35.68%

Unintended Consequences
No unintended consequences to individuals or populations have been identified during testing, and no evidence of unintended negative consequences to individuals or populations have been reported since implementation.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

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If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
3,218 acute care hospital providers

Estimate of Annual Improvement in Measure Score
N/A

Type of Evidence to Support the Measure
Systematic Review; Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted; Stratified

Are social determinants of health built into the risk adjustment model?
No

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
N/A

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
The patients/caregivers that were part of the standard Technical Expert Panel (TEP) were engaged once, at the onset of the re-evaluation process for the measure.

Total Number of Patients and/or Caregivers Consulted
2

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
2:18

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2

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Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
18

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
18

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
0

Measure Testing Details

Reliability Testing Interpretation of Results
The correlation coefficients for scores across the 2018 and 2017 performance periods were lower than scores compared across the randomly split 2018 performance period sample. This difference is expected as the two-year sample may capture additional variation in hospital performance across performance periods. The Shrout-Fleiss intraclass correlation coefficients were similar to the Pearson correlation coefficients at 0.83 and 0.79 for the 2018 split-sample and 2017 and 2018 sample. As ICC(2,1) imposes a

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common variance for provider across samples, its use is most appropriate in assessing the reliability of the 2018 performance period random split-sample.

Overall, the reliability of the MSPB Hospital measure is high, including when its current 25-episode minimum is applied to balance measure reliability and inclusiveness. The MSPB Hospital measure performance period episode minimum is 25 for the HVBP program, and the signal-to-noise analysis indicates that this episode minimum maintains the measure's high reliability.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise; ICC (Intraclass correlation coefficient)

Reliability Testing Sample Size
3,148 hospitals

Reliability Testing Statistical Result
Reliability Score Results: The signal-to-noise analysis sought to determine the extent to which variation in the measure is due to true, underlying provider performance, rather than variation within provider, from provider episodes. The closer a reliability score is to 1.0, the larger the between-group variance is relative to the within-group variance, the greater the suggestion that the measure is capturing the systematic differences between hospitals. The average reliability score of hospitals with at least 25 episodes was 0.92. The median reliability score for hospitals with at least 25 episodes was 0.96 and the reliability score interquartile range spanned from 0.91 to 0.98. While higher episode-minima yield higher reliability results, the application of higher episode-minimums reduces the number of providers receiving a measure score. Additionally, 99.0 percent of providers met or exceeded a 0.4 reliability score, a standard generally considered as the threshold for 'moderate' reliability, and 94.3 percent of providers met or exceeded a 0.7 reliability score.

Split-sample Reliability Testing Results: The multi-sample testing examined agreement between two hospital measure scores from (1) a randomly split set of episodes in the 2018 performance period and (2) the 2018 and 2017 performance periods. We analyzed score agreement from Pearson and Shrout-Fleiss intraclass correlation coefficients ICC(2,1). Coefficients close to 1.0 indicate high agreement in scoring between samples and suggest that performance scores are identified more by provider characteristics, like efficiency of care, than by random variation. The Pearson correlation coefficient was 0.83 for the 2018 split-sample and 0.79 for the 2017 and 2018 sample. The Shrout-Fleiss intraclass correlation coefficients were similar at 0.83 and 0.79 for the 2018 split-sample and 2017 and 2018 sample, respectively.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
Yes

If yes, specify the number of cases and the percentage of providers
A case minimum of 25 episodes per hospital was applied for the reliability testing.98 percent of hospitals met the minimum denominator requirement. Specifically, there were 3,218 acute care hospital providers with an MSPB Hospital measure score in 2018. For the reliability testing, the sample was restricted to 3,148 providers who met the 25 episode case minimum that is currently imposed on the MSPB Hospital measure under the Hospital VBP program.

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Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Correlation; Face Validity

Validity Testing Sample Size
5,965,189 episodes (from 3,148 hospitals that met the 25-episode case minimum)

Validity Testing Statistical Result
Face Validity: The potential measure refinements were tested by the measure developer and reviewed by a technical expert panel in February 2020 as part of the MSPB Hospital measure's re-evaluation. The TEP comprised 20 members with expertise in cost measure development and evaluation and quality improvement from diverse backgrounds, including clinicians, healthcare providers, academia, and patient advocacy organizations. Though no official vote was taken, panelists agreed that maintaining MSPB Hospital measure's holistic "all-cost" approach, allowing readmissions to trigger new MSPB Hospital episodes to increase measure surveillance, and updating the MSPB Hospital measure's MSPB Amount (score numerator) calculation to evenly weight all of a hospital's episodes were appropriate refinements. Panelists further provided additional considerations for ongoing social risk factor testing, like examining the impact of controlling for the Area Deprivation Index.

Observed to Expected Cost Ratios: For this analysis, the relationship between risk-adjusted episode cost ratios and episodes with and without post-admission events that are known indicators of high cost or intensive care was examined. Specifically, the developer examined the observed to expected cost (O/E) ratios of episodes with acute care readmissions, episodes with any post-acute care (PAC) facility use, and episodes with PAC skilled nursing facility (SNF) use. The developer examined episodes with PAC-SNF use separately as such use has traditionally accounted for the largest share of Medicare's fee-for-service PAC expenditures. The mean, standard deviation, and percentile distribution of observed to expected (O/E) episode cost ratios for episodes with high-cost post-admission events, such as readmissions or post-acute care, were higher than their counter parts. For example, episodes with an acute care re-hospitalization an average O/E ratio of 1.55 and an interquartile range of 1.07 to 1.85, while episodes without such readmissions had an average O/E ratio of 0.89 and an interquartile range of 0.60 to 1.02. Service Utilization: For this analysis, the relationship between a hospital's average expected episode cost (the average "E" in O/E cost ratios) and average episode rates of several service use categories was examined. Per episode service use, particularly for higher cost events or events that require further care, like surgical procedures, may be positively correlated with expected episode costs if the regression model that the MSPB Hospital measure uses for risk adjustment predicts patient need for such services well. Most service use/setting categories were moderately and positively correlated to the average predicted episode cost, with the correlations across all services categories average +0.487 and procedure use evidencing the strongest correlation (+0.721).

Correlations with Other Measures: For this analysis, the relationship between the MSPB Hospital measure and other cost-specific measures, efficiency-related measures, and measures in other HVBP program domains was examined. Specifically, the analysis compared MSPB Hospital measure components that may more closely relate to other measure scores and rates. For example, it compared the average expected episode amount to other measure performance period rates, for measures that had a literature-based or hypothesized conceptual relationship to the MSPB Hospital measure. All three Payment & Value of Care measures, capturing 30-day Medicare payments for acute myocardial infarction, heart failure, and pneumonia conditions, were positively and weakly (or moderately)

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correlated with the hospital average predicted episode cost. All four Timely & Effective Care measures, capturing time spent in the ED before being sent home or admitted, were also positively and weakly or moderately correlated with average predicted episode costs.

Validity Testing Interpretation of Results

Observed to Expected Cost Ratios: As expected, the average O/E cost ratio for episodes with downstream events that are of high resource, like readmissions or PAC use, are higher than episodes without such events.

Service Utilization: Although the hypothesized positive relationship between a hospital's average predicted episode cost and average episode rates of service use may not be linear or strong as high service use may be comprised of low-cost services relative to higher cost alternative services (consider, for example, the substitution between a high E&M visits per episode rate for regular patient check-ups versus a low but costly adverse event, like emergency surgery), the positive correlations evidenced are in line with the expectations.

Correlations with Other Measures: The relationship between the MSPB Hospital measure's risk-adjusted episode cost and other cost, efficiency, outcome, and quality measures are largely in line with hypothesized and literature-based expectations. Similar to the MSPB Hospital measure, the three Payment & Value of Care measures analyzed are triggered by an index hospitalization and consider standardized amounts. Unlike the MSPB Hospital measure, the episode window for these measures run 30-days from hospitalization – instead of 30-days after hospital discharge and are specific to hospitalizations that have principal discharge diagnoses of Acute Myocardial Infarction, Heart Failure, or Pneumonia. Importantly, these measures also prorate claim payments to their 30-day episode window and consider patient populations that expired, while the MSPB Hospital Measure does neither and these measures differ in their risk adjustment model methods. With these differences, however, we capture an expected positive rank correlation with these condition-specific cost measures. Further, the positive rank correlation between a hospital's average expected episode cost and non-cost measures of inefficiency (e.g. Emergency Department wait time) is in-line with existing literature. The rank correlations with other measures used in the FY2019 HVBP program and the MSPB Hospital measure's average expected cost are also in line with expectations. Literature has found, for example, that hospital acquired infections are associated with higher Medicare costs and this recognition is not new, with CMS ceasing payment for select HAIs in the past. Other literature has also noted the positive relationship between reported patient satisfaction and efficiency outcomes, like shorter stays, lower readmissions, and lower mortality rates, that can influence cost.

Measure performance – Type of Score

Ratio

Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

Given that the MSPB Hospital is a claims-based measure, there is no submission method for the measure. Based on the analysis of all IPPS eligible hospitals with at least 25 episodes for the 2018 performance period, the MSPB Hospital measure score has the following distributional characteristics:

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- Mean: 0.99, standard deviation: 0.08
- Median: 0.99
- Min: 0.49, max: 1.68
- Interquartile range spans from 0.94 to 1.03

Benchmark, if applicable
The benchmark is the average (mean) performance on the MSPB Hospital measure of the top 10% of hospitals during the baseline period.

Measure Contact Information

Measure Steward
Centers for Medicare & Medicaid Services

Measure Steward Contact Information
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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-131 Medicare Spending Per Beneficiary (MSPB) Hospital

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes
Justification and Notes: The Hospital Value-Based Purchasing (HVBP) program is statutorily required to include a cost efficiency measure; at present, that measure is Medicare Spending per Beneficiary (MSPB). This Measure Under Consideration is a methodological refinement to the current

MSPB measure, by equal-weighting all risk-adjusted hospital episodes, expanding the coverage of included episodes, and updating the risk-adjustment model to account for these expanded episodes.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes: The MSPB measure compares a hospital's episode costs to the national median hospital's episode costs, both on a risk-adjusted basis. According to MedPAC's 2020 report on Medicare payments, Medicare spending for inpatient care at short-term acute care hospitals amounted to $121 billion, a growing figure. To control costs, MedPAC recommended incentivizing stronger coordination of care to prevent readmissions and other costly hospital episodes, which this measure specifically addressed. For example, hospitals could coordinate with post-acute care providers to reduce adverse events after discharge, or shift post-acute spending to home health.

Does the measure address a quality challenge?
Yes/No: Yes
Justification and Notes: Performance data for hospitals on the MSPB measure in 2018 showed substantial variation in scores, suggesting an opportunity for improvement for lower-performing hospitals. In the 20th percentile of performance (where lower is better), hospitals spent 93% of the median hospital, whereas the 80th percentile spent 105% as much as the median hospital – indicating a 13% possible spending reduction if the lowest-performing hospitals were to improve to the level of the highest-performing hospitals. In practice, this would represent tens of billions of dollars in reduced Medicare costs.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes
Justification and Notes: The Measure Under Consideration is the only cost and resource use measure in the HVBP program, and, as the only measure in the Efficiency and Cost Reduction Domain, constitutes fully 25% of the total score for hospitals reporting to that quality program. Over 3,000 hospitals were given a MSPB measure score in 2019, underpinning the broad applicability of the measure.

Can the measure be feasibly reported?
Yes/No: Yes
Justification and Notes: The measure is based on administrative claims that are available electronically. No feasibility issues were reported in prior years of implementation in the HVBP program.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: Yes
Justification and Notes: The Measure Under Consideration, a methodological refinement to the MSPB measure currently included in the program, was endorsed by the National Quality Forum in June 2021. The measure was specified for and tested in the hospital care setting, at the facility level of analysis, consistent with the HVBP program implementation.

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?
Yes/No: No
Justification and Notes: Over several years of implementation, and two reviews for endorsement by NQF's Consensus Development Process (CDP), no negative unintended consequences were identified.

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MAP Rural Health Advisory Group Input:

Relative priority/utility:

- There was discussion that this measure is not addressing the needs of a number of rural hospitals; however, the developer clarified that there are some critical access hospitals in the measure
- The measure was removed from IQR to make room for the updated version. This updated version of the measure would go first to HIQR for public reporting, and then eventually replace the MSPB Hospital measure in the HVBP program

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.

Average: 3.7
1 – 0 votes
2 – 0 votes
3 – 3 votes
4 – 7 votes
5 – 0 votes

MAP Health Equity Advisory Group Input:

The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity

Average: 3.2
1 – 0 votes
2 – 4 votes
3 – 6 votes
4 – 7 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

Summary: What is the potential value to the program measure set?

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This Measure Under Consideration is a methodological refinement to the Medicare Spending Per Beneficiary measure currently in HVBP per statutory requirement. The updated measure now equal-weights all risk-adjusted hospital episodes, expands the coverage of included episodes, and updates the risk-adjustment model to account for these expanded episodes.

Summary: What is the potential impact of this measure on quality of care for patients?
Performance data from prior years of implementation of this measure indicates a substantial opportunity for improvement: there is a considerable range in costs for episodes of care across U.S. hospitals. This measure, one of the only cost measures used in federal quality program reporting, will continue to incentivize hospitals to identify methods of cost savings such as care coordination initiatives and patient safety initiatives to reduce the number of costly adverse events.

Section 3: Public Comments

Federation of American Hospitals
The Federation of American Hospitals (FAH) noted during the recent National Quality Forum (NQF) review of this measure that the Centers for Medicare and Medicaid Services (CMS) did not provide an adequate justification on why the weighting of all risk-adjusted hospital episodes were changed nor was any rationale provided on the expansion of episodes to include re-hospitalizations within 30 days of discharge of any admission that opens an episode. We are particularly concerned with the inclusion of re-hospitalizations as a trigger episode since the same costs will now be attributed twice to a hospital. Double counting of costs is inappropriate and provides misleading information to providers and patients.

In addition, we continue to question the scientific acceptability of the measure based on the risk model's fit with the unadjusted and adjusted R-squared ranging from 0.11 to 0.67 across the Major Diagnostic Categories. The FAH does not believe that the reasons for this result were adequately addressed and risk adjustment must be improved.

Furthermore, while the FAH appreciates that social risk factors were reviewed, we remain concerned with the risk adjustment approach to determine whether inclusion of social risk factors. The FAH believes that this approach should not consider the identification and testing of social risk factors as supplementary to clinical risk factors. This approach was identified as a concern by the NQF Disparities Standing Committee and developers must begin to include these factors within the testing of the model rather than the approach of "adding on" factors after the model is developed. This type of analysis would assist facilities and others in understanding how their inclusion could impact the model and provide additional information for groups examining this issue such as the NQF and Office of the Assistant Secretary for Planning and Evaluation. Even with testing of the social risk factors after the clinical risk factors, analyses showed that hospitals' measure scores shift when some or all of the social risk factors are applied within the risk model and particularly just over 15% of safety-net hospitals moved above or below the delta. This shift should lead CMS to reconsider inclusion of some or all of the variables in the risk model.

In addition, CMS must address the duplicate reporting of the measure results as these revisions are implemented in either program. The potential for misleading and/or inaccurate information must be

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avoided at all costs. As a result, the FAH requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

American Medical Association

The American Medical Association (AMA) is concerned that the changes to equally weight all risk-adjusted hospital episodes by the average ratio of observed to expected costs and expand episodes to include re-hospitalizations within 30 days of discharge of any admission that opens an episode have not been sufficiently justified. No rationale was provided for any of these changes during the recent review by the National Quality Forum or in this submission, which makes it difficult for us to provide input and determine whether we agree or have concerns with the changes. For example, it remains unclear to us whether the expansion to include readmissions will now double count the costs attributed to a hospital.

In addition, the AMA continues to believe that the current risk adjustment model is not adequate due to the unadjusted and adjusted R-squared results ranging from 0.11 to 0.67 across the Major Diagnostic Categories nor is the measure adequately tested and adjusted for social risk factors. It is unclear to us why the developer would test social risk factors after adjusting for clinical risk factors rather than assessing the impact of both clinical and social risk factors in the model at the same time. These variations in how risk adjustment factors are examined could also impact how each variable (clinical or social) perform in the model and remain unanswered questions. In addition, we note in the information submitted to NQF hospitals’ measure scores shifted when some or all of the social risk factors are applied within the risk model and particularly just over 15% of safety-net hospitals moved above or below the delta.

Furthermore, we ask that the MAP include a condition recommending that the Centers for Medicare and Medicaid Services (CMS) halt reporting of the existing measure including any public release of performance results. Continued use of the existing measure is inappropriate and could produce conflicting information to providers and patients.

As a result, the AMA believes that these concerns must be addressed prior to implementation of this revised measure and requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

Premier, Inc.

Premier conditionally supports adoption of this refined measure. CMS should seek endorsement before moving forward with the measure.

American Heart Association

The MUC list documentation mentions that there will be significant changes to this measure. However, we are unable to provide comments on those changes since the specification changes have not been made available. Therefore, the AHA does not support the MAP’s recommendation to support this measure for rulemaking.

Johnson & Johnson

Johnson & Johnson agrees with the MAP's support for rulemaking for this measure. Johnson & Johnson agrees with the importance of evaluating and understanding Medicare beneficiaries cost of care. Even more critical is evaluating the value of care provided. Determining the value of care cannot be reduced to the evaluation of its cost. We therefore emphasize the importance of pairing measurement of individual Medicare spending in measures of total cost of care with an appropriate time horizon to understand the true value of diagnostics and treatment – upfront costs to Medicare and patients, if

associated with appropriate care, will ideally translate into value via reductions in higher cost treatment. It is critical to ensure that measurement of individual Medicare spending be paired with measures of high-quality care that evaluates whether appropriate evidence-based services that achieve optimal clinical outcomes for patients were provided. Measuring cost and quality of care in the context of meaningful patient-centered measures is critical; this must go beyond evaluating satisfaction with experience of care and evaluate the extent that providers are collaborating with patients on goals of care, that those goals of care were met, and that meaningful patient-reported outcomes (such as quality of life and functional status) and clinical endpoints (survival, reducing disease progression) were achieved. We encourage CMS to explore the extent to which unintended consequences may be a risk, such as incentivizing reductions in access to new therapies. We are concerned that specification changes to the measure that would allow hospital readmissions to trigger new MSPB episodes, where novel therapies will lead to expected readmissions to manage severe treatment adverse events.

American Medical Association

The American Medical Association (AMA) continues to have concerns with how this measure is specified and the inadequate risk adjustment testing. As a result, the AMA believes that these concerns must be addressed prior to implementation of this revised measure and requests that the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

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Medicare Promoting Interoperability Program for Hospitals

MUC2021-084 Hospital Harm – Opioid-Related Adverse Events

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Medicare Promoting Interoperability Program for Hospitals, Hospital Inpatient Quality Reporting (IQR) Program

Workgroup
Hospital

Measure Description
This measure assesses the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. This measure excludes opioid antagonist (naloxone) administration occurring in the operating room setting.

Numerator
Inpatient hospitalizations where an opioid antagonist (naloxone) was administered outside of the operating room and within 12 hours following administration of an opioid medication. Only one numerator event is counted per encounter.

Numerator Exceptions
N/A

Denominator
Inpatient hospitalizations for patients 18 years or older during which at least one opioid medication was administered. An inpatient hospitalization includes time spent in the emergency department or in observation status when the patients are ultimately admitted to inpatient status.

Denominator Exclusions
N/A; there are no denominator exclusions

Denominator Exceptions
N/A

State of development
Fully Developed

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State of Development Details
N/A

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Other: Not specialty specific

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Electronic Health Record

If applicable, specify the data source
N/A

If EHR 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?
Community hospital; Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
6032

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Submitted

NQF ID Number
NQF # 3501e

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If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
2021

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
Yes

If eCQM, enter Measure Authoring Tool (MAT) number
819

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
Yes

If eCQM, does any electronic health record (EHR) system tested need to be modified?
Yes

If yes, how would you describe the degree of effort?
4

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
Yes

Previous Measure Information
Year: 2017

Measure ID: MUC17-210

Workgroups: NQF MAP Hospital Workgroup December 2017

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Program: 2017- Hospital Inpatient Quality Reporting Program

Recommendation: 2017- Refine and resubmit

MAP noted that this measure concept assesses a critical patient safety issue that should be addressed with urgency. However, MAP raised concerns that the measure has not been tested in enough hospitals to assess measure reliability and validity across facilities, and noted that further testing should be completed before it is implemented in the program. As the measure developer completes testing of the measure, MAP requested that the developer consider the impact of chronic opioid users and patients receiving Suboxone (buprenorphine and naloxone). MAP noted that the completed testing should demonstrate reliability and validity before the measure is submitted to NQF for review and endorsement. MAP recommended that the Patient Safety Standing Committee pay special attention to potential unintended consequences and noted there may be a need to balance this measure with measures assessing appropriate use of naloxone and adequate pain control.

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What is the history or background for including this measure on the new measures under consideration list?

Measure previously submitted to MAP, refined and resubmitted per MAP recommendation

Range of years this measure has been used by CMS Programs

N/A

What other federal programs are currently using this measure?

N/A

Is this measure similar to and/or competing with a measure(s) already in a program?

Yes

Which measure(s) already in a program is your measure similar to and/or competing with?

NQF #3389: Concurrent Use of Opioids and Benzodiazepines (COB)

NQF #3316e: Safe Use of Opioids- Concurrent Prescribing

How will this measure be distinguished from other similar and/or competing measures?

The Hospital Harm – Opioid-Related Adverse Events eCQM, the Safe Use of Opioids – Concurrent Prescribing Measure (NQF #3316e), and the Concurrent Use of Opioids and Benzodiazepines (NQF #3389) all have the same general target population, which are adult patients who receive opioids. However, the focus of each measure is very different. The Hospital Harm – Opioid-Related Adverse Events eCQM focuses on patients who receive excessive doses of opioids during their hospitalization and, subsequently, require naloxone to prevent further patient harm. In contrast, NQF #3316e focuses on patients who receive concurrent opioid or opioid and benzodiazepine prescriptions at discharge, putting them at risk of adverse drug events after hospital discharge, and NQF #3389 tracks concurrent opioid and benzodiazepine outpatient prescriptions. As a result of the varying measure focuses, the Hospital Harm – Opioid-Related Adverse Events eCQM has a broad denominator of all inpatient adults >18 years who received a hospital administered opioid, while NQF #3316e has a more narrow denominator of adults >18 years prescribed an opioid or benzodiazepine at discharge from a hospital-

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based encounter. NQF #3316e also excludes patients with an active cancer diagnosis, palliative care order, or length of stay >120 days. NQF #3389 addresses outpatient prescription claims and excludes patients in hospice, or with cancer or sickle cell disease diagnosis.

How will this measure add value to the CMS program?

The Hospital Harm – Opioid Related Adverse Events eCQM focuses on patients who receive excessive doses of opioids during their hospitalization and, subsequently, require naloxone to prevent further patient harm. This approach will complement the similar other measures in place that focus on the outpatient population.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute

N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Opioids are often the foundation for sedation and pain relief. However, use of opioids can also lead to serious adverse events, including constipation, oversedation, delirium, and respiratory depression. Opioid-related adverse events have both patient-level and financial implications. Patients who experience this event have been noted to have 55% longer lengths of stay, 47% higher costs, 36% higher risk of 30-day readmission, and 3.4 times higher payments than patients without these adverse events (Kessler et al., 2013).

Most opioid-related adverse events are preventable. Of the adverse drug events reported to the Joint Commission´s Sentinel Event database, 47% were due to a wrong medication dose, 29% to improper monitoring, and 11% to other causes (e. g., medication interactions, drug reactions) (Joint Commission, 2012; Overdyk, 2009). Additionally, in a closed-claims analysis, 97% of adverse events were judged preventable with better monitoring and response (Lee et al., 2015). Naloxone administration is often used as an indicator of a severe opioid-related adverse event, and implementation of this measure can advance safe use of opioids in hospitals and prevent these serious and potentially lethal adverse drug events. Naloxone is an opioid reversal agent typically used for severe opioid-related adverse events. Naloxone administration has been used in a number of studies as an indicator of opioid-related adverse events (Nwulu et al., 2013; Eckstrand et al., 2009).

From Part 10 of the 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care (Lavonas et al., 2015), the following recommendation is listed for use of Naloxone :

Naloxone is a potent opioid receptor antagonist in the brain, spinal cord, and gastrointestinal system. Naloxone has an excellent safety profile and can rapidly reverse central nervous system (CNS) and respiratory depression in a patient with an opioid-associated resuscitative emergency.

References:

Eckstrand, J. A., Habib, A. S., Williamson, A., Horvath, M. M., Gattis, K. G., Cozart, H., & Ferranti, J.

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Computerized surveillance of opioid-related adverse drug events in perioperative care: a cross-sectional study. Patient Saf Surg. 2009;3(1), 18.

Kessler ER, Shah M, Gruschkus SK, Raju A. Cost and quality implications of opioid-based postsurgical pain control using administrative claims data from a large health system: opioid-related adverse events and their impact on clinical and economic outcomes. Pharmacotherapy. 2013;33(4):383-391.

Lavonas EJ, Drennan IR, Gabrielli A, Heffner AC, Hoyte CO, Orkin AM, Sawyer KN, Donnino MW. Part 10: Special Circumstances of Resuscitation: 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. Circulation. 2015 Nov 3;132(18 Suppl 2):S501-18. doi: 10.1161/CIR.0000000000000264. Erratum in: Circulation. 2016 Aug 30;134(9):e122.

Lee, L. A., Caplan, R. A., Stephens, L. S., Posner, K. L., Terman, G. W., Voepel-Lewis, T., & Domino, K. B. Postoperative opioid-induced respiratory depression: a closed claims analysis. Anesthesiology. 2015:122(3), 659-665.

Nwulu, U., Nirantharakumar, K., Odesanya, R., McDowell, S. E., & Coleman, J. J. Improvement in the detection of adverse drug events by the use of electronic health and prescription records: an evaluation of two trigger tools. Eur J Clin Pharmacol. 2013;69(2), 255-259.

Overdyk FJ: Postoperative respiratory depression and opioids. Initiatives in Safe Patient Care, Saxe Healthcare Communications, 2009 The Joint Commission. Safe use of opioids in hospitals. Sentinel Event Alert. 2012(49):1-5. https://www.jointcommission.org/-/media/deprecated-unorganized/imported-assets/tjc/system-folders/topics-library/sea_49_opioids_8_2_12_finalpdf.pdf?db=web&hash=0135F306FCB10D919CF7572ECCC65C84

For additional evidence please see the ORAE evidence attachment.

Evidence that the measure can be operationalized

This is an eCQM that uses all data elements from defined fields in the EHR. Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the OR rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs. For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction. Test sites' decisions to document opioid administration inside of the OR on paper can be driven by many factors, one of which is a workflow preference. Since all hospital-based EHR vendor systems offer anesthesia modules, there should be no technical limitation in transitioning paper-based documentation to electronic documentation. Given that non-anesthesia-related opioid administrations are already captured electronically, we are optimistic that measure implementation is still feasible. Moreover, measure implementation will drive workflow changes toward electronic capture within the OR.

How is the measure expected to be reported to the program?

eCQM

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Feasibility of Data Elements

ALL data elements are in defined fields in electronic health records (EHRs)

Evidence of Performance Gap

The rate of ORAE estimated using the patient EHR data from calendar year 2019 were within the range of harm rates found in the literature, which was between 0.1% and 1.3% among studies using naloxone administration as a surrogate measure of respiratory depression (Cashman, 2004). The relatively wide variability in the rate of ORAE across the six sites demonstrates that there exists room for improvement in reducing the ORAE among at-risk patients.

ORAE measure performance rates ranged from 0.11% (for every 1,000 qualified hospital admissions there are 1.1 inpatient encounters where patients suffered ORAE) to 0.45% (for every 1,000 qualified hospital admissions there are 4.5 inpatient encounters where patients suffered ORAE), indicating ample room for quality improvement in hospital inpatient environment. Also, larger hospitals (e.g., test sites 4 to 6), though having more numerator admissions, do not necessarily have higher ORAE rates. This suggests that all hospitals, irrespective of size, need to follow best practices in patient care to prevent ORAE.

Reference:

Cashman, J. N., and S. J. Dolin. "Respiratory and haemodynamic effects of acute postoperative pain management: evidence from published data." British Journal of Anaesthesia 93, no. 2 (2004): 212-223.

For more information see ORAE MIF and ORAE Evidence Attachment.

Unintended Consequences

We did not identify any unintended consequences during eCQM development or testing. However, CMS is committed to monitoring this eCQM's use and assessing potential unintended consequences over time, such as the inappropriate shifting of care and other negative unintended consequences for patients. However, it is important that the eCQM, as currently specified, does not detect false positives. To verify this, we conducted empirical tests to examine whether numerator cases identified by the measure are true positives. In the chart review (or parallel-form comparison) process we instructed clinical abstractors to extract both indications for and patient subsequent responses to the naloxone administration. We found that the predominant rationale for subsequent naloxone administration was that patients were somnolent or unresponsive, with the second mostly cited reason being opiate reversal. In terms of patient responses to naloxone administration, we found that the most frequently documented was: patient showed clear signs of response to naloxone administration. This qualitative evidence solidifies the evaluation of measure logic and suggests that the measure can correctly predict a true positive.

Outline the clinical guidelines supporting this measure

Two evidence-based guidelines directly support the measure focus as follows.

- Jungquist CR, Quinlan-Colwell A, Vallerand A, et al. American Society for Pain Management Nursing Guidelines on Monitoring for Opioid-Induced Advancing Sedation and Respiratory Depression: Revisions. Pain Manag Nurs. 2020 Feb;21(1):7-25. Epub 2019 Jul 31.
- This guideline is evidence-based and recommends that clinicians recognize that all hospitalized patients receiving systemic (e.g., transdermal, IV, oral) or neuraxial opioids for acute pain

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management are at risk of opioid-induced unintended advancing sedation and opioid-induced respiratory depression.

- The panel also recommended that all patients who will receive opioids undergo a comprehensive assessment of level of individual risk before initiation of opioid therapy. Ongoing reassessment of risk that continues through the trajectory of clinical care is essential (strong recommendation, moderate level evidence).
- The panel recommends that clinicians employ evidence-based pain management that incorporates opioid-sparing and multimodal analgesia therapies (strong recommendation, high-level evidence)
- Practice Guidelines for the Prevention, Detection, and Management of Respiratory Depression Associated with Neuraxial Opioid Administration: An Updated Report by the American Society of Anesthesiologists Task Force on Neuraxial Opioids and the American Society of Regional Anesthesia and Pain Medicine. Anesthesiology. 2016 Mar;124(3):535-52.
- This guideline is evidence-based and recommends identification of patients with risk factors for respiratory depression includes conducting a focused history (e.g., reviewing medical records) and physical examination;
- Prevention of respiratory depression includes consideration of noninvasive positive pressure ventilation and drug selection.
- Monitoring all patients receiving neuraxial opioids for adequacy of ventilation (e.g., respiratory rate, depth of respiration [assessed without disturbing a sleeping patient]), oxygenation (e.g., pulse oximetry when appropriate), and level of consciousness.
- Increased monitoring (e.g., intensity, duration, or additional methods of monitoring) may be warranted for patients at increased risk of respiratory depression (e.g., unstable medical condition, obesity, obstructive sleep apnea, concomitant administration of opioid analgesics or hypnotics by other routes, extremes of age).

For additional information see the detailed ORAE Evidence Attachment.

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
American Society of Anesthesiologists, American Society for Pain Management

If yes, what was the grade?
Strong recommendation, high evidence

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine

Estimate of Annual Improvement in Measure Score
N/A

Type of Evidence to Support the Measure
Clinical Guidelines; Empirical data

Is the measure risk adjusted, stratified, or both?
None

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Are social determinants of health built into the risk adjustment model?
N/A

Estimated Cost Avoided by the Measure
N/A

Estimate of Average Cost Savings Per Event
N/A

Cost Avoided Annually by Medicare/Provider
N/A

Source of Estimate
None

Year of Cost Literature Cited
N/A

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
Yes

If yes, choose all methods of obtaining patient/caregiver information
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
Patient/ caregivers were engaged a total of three times. Once during conceptualization and twice at the conclusion of specification.

Total Number of Patients and/or Caregivers Consulted
2

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
1:5

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
2

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

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If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Standard TEP

Total Number of Clinicians/Providers Consulted
5

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
5

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
23

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
11

Measure Testing Details

Reliability Testing Interpretation of Results
The results suggest that all critical data elements are reliably and consistently captured in patient EHRs and that there is a strong concordance between data extracted from the EHR electronically and the data extracted from patient medical records manually (“gold standard”).

Type of Reliability Testing
Data Element Reliability

Reliability Testing: Type of Testing Analysis
Signal to Noise; IRR (Inter-rater reliability); Other: frequency of missing or erroneous data for critical

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data elements

Reliability Testing Sample Size
6 test sites

Reliability Testing Statistical Result
Cohen's Kappa coefficient was calculated for all 5 critical data elements for each of the six test sites. The Kappa coefficients across 5 of the 6 test sites were 1 for all of the critical data elements. For the 5th test site, two of the data elements had a Kappa coefficient of .98.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Face Validity; Predictive Validity

Validity Testing Sample Size
100 qualified admissions for each of the six implementation test sites.

Validity Testing Statistical Result
See Tables 8 -14 and Figures 2 and 3 in section 2b1.3 of the ORAE NQF Testing Attachment document.

Validity Testing Interpretation of Results
Data Element Validity

Across the six implementation test sites, all but two data elements showed a match rate of 100%, indicating that valid and accurate data were extracted from patient EHRs. The exceptions in test site 5 were due to a documentation preference. As we discussed in section 2b1.3, across the 155 (49 + 56 + 50) denominator-only cases from test sites 4 to 6 who share the same documentation pattern inside of the OR, we found only one misaligned case. The low false-negative rate provides some degree of confidence that the issue is not widely seen in the harm event the current measure seeks to identify. Moreover, for hospitals that utilize eMARs throughout, this misalignment will be eliminated. Because all hospital-based EHR vendor systems offer anesthesia modules that can document medication electronically, there should be no technical limitation in transitioning from paper-based documentation to electronic documentation.

Measure Score Validity

Across the six implementation test sites, PPV is 100%, suggesting that in all cases the qualified admissions have met the criteria for an ORAE in both the chart-abstracted and EHR-extracted data.

Sensitivity is 100% in all but one test site. This means that the probability of EHR detecting an ORAE in patients who had a true ORAE is close to 100%. Similarly, NPV is 100% in all but one test site. This

suggests that the probability of EHR detecting an at-risk patient was also a patient at risk for ORAE based on the abstracted data is near perfect. Specificity is 100% in all test sites, indicating that the probability of correctly classifying an at-risk patient when the patient is truly and solely at risk for ORAE is 100%.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
In testing, the measure performance rates ranged from 0.11% (for every 1,000 qualified hospital admissions there are 1.1 inpatient encounters where patients suffered ORAE) to 0.45% (for every 1,000 qualified hospital admissions there are 4.5 inpatient encounters where patients suffered ORAE), indicating ample room for quality improvement in hospital inpatient environment. Standard deviations ranged from 3.30% to 6.71%.

Benchmark, if applicable
N/A

Measure Contact Information

Measure Steward
Centers for Medicare & Medicaid Services

Measure Steward Contact Information
Annese Abdullah-Mclaughlin
7500 Security Boulevard
Baltimore, MD 21244
annese.abdullah-mclaughlin@cms.hhs.gov
(410)786-2995

Long-Term Measure Steward
N/A

Long-Term Measure Steward Contact Information
N/A

Primary Submitter Contact Information
Hannah Klein
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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-084 Hospital Harm – Opioid-Related Adverse Events

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure aligns with the CMS Needs and Priorities Meaningful Measures 2.0 focus on patient safety. It will be the only measure within this program to assess the proportion of inpatient hospital encounters where patients ages 18 years of age or older have been administered an opioid medication, subsequently suffer the harm of an opioid-related adverse event, and are administered an opioid antagonist (naloxone) within 12 hours. As an eCQM outcome measure for a high-priority condition, alignment across programs will be achieved because all Hospital Inpatient Quality Reporting Program eCQMs are reportable in the Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This is an outcome measure that calculates the proportion of inpatient events in which patients receiving opioid medications suffer an ORAE that must be addressed with an opioid antagonist (naloxone) within 12 hours following the administration of the medication. ORAEs may be prevented or reduced with the use of appropriate pain management techniques, education and training, and patient monitoring (Premier Safety Institute, 2021; The Joint Commission, 2012). The administration of opioid antagonists has been used as an identification method for ORAEs (Nwulu et al., 2012; Shafi et al., 2018).

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: The measure addresses a serious reportable event (ORAEs). Opioids have been identified among the drugs most commonly associated with adverse drug events (The Joint Commission, 2012) and ORAEs are associated with increased hospital costs, length of stay, readmissions, and mortality (Kessler et al., 2013; Shafi et al., 2018). The developer notes that the rate of ORAE across testing sites ranged from 0.11% to 0.45%. The NQF Patient Safety Standing Committee reviewed this measure in Spring Cycle 2021 and acknowledged the four-fold differences across the six sites tested (measure rates ranging from 0.11 to 0.45 percent). However, the NQF Standing Committee did express concern with the low absolute measure rate and whether the low number of events showed meaningful differences across sites. The measure developers identified variability in performance by age, sex, race, ethnicity, and payer source, which following national implementation of the measure may uncover additional performance gaps among vulnerable populations.

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Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: While the developer has identified two existing measures that address opioid medication prescriptions (NQF #3389 and NQF #3316e), the Hospital Medicare Promoting Interoperability Program for Hospitals does not have a measure that addresses ORAEs during an inpatient visit. NQF #3316e addresses concurrent opioid/opioid and benzodiazepine prescriptions at discharge, while NQF#3389 measures the percentage of patients with concurrent opioid and benzodiazepine prescriptions and is not active in any Medicare program.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The eCQM is fully specified, and the developer notes that all required data elements are readily available in electronic health records. The developer conducted feasibility testing and a provider workflow analysis and found that no adjustments were required to provider workflow to report the data. During the recent NQF Standing Committee review, concerns were raised that there may be feasibility challenges with anesthesiologists documenting naloxone use on paper charts. Of all sites used for the measure feasibility assessment, some reported that their anesthesiologists document their activities on paper-based anesthesia records inside of the operating room (OR) rather than via the electronic medication administration record (eMAR). This suggests that, at this time, for these sites, opioid and naloxone administration inside of the OR will not be available for structured electronic extraction or appear in patient EHRs. For opioid and naloxone administration outside of OR suite, however, all test sites confirmed that they are documented in the eMARs, and available for electronic extraction. Noting this consideration, the measure passed feasibility criteria for the Patient Safety Standing CDP Committee when reviewed in the Spring 2021 review cycle.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: The measure is fully specified and tested at the facility level of analysis in hospital and acute care settings. This measure was previously submitted for endorsement review in spring 2019 and was substantially updated since the initial submission. The measure has been re-submitted with updated specifications for endorsement review by the NQF Patient Safety Standing Committee in the Consensus Development Process (CDP) Spring Cycle 2021 and passed criteria for scientific acceptability. The NQF CSAC has voted to uphold the Standing Committee's decision to endorse the measure.

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?

Yes/No: N/A

Justification and Notes: This measure is not currently in use and no unintended consequences were identified by the developer during testing. The developer conducted additional testing to verify that the measure would not detect false positives.

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PAC/LTC Core Concept?
Yes/No: N/A

Justification: N/A

Impact Act Domain
Yes/No: N/A

Justification: N/A

Hospice High Priority Areas
Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- This is a good measure and no adverse effect/issues on rural institutions

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.2
1 – 0 votes
2 – 0 votes
3 – 0 votes
4 – 11 votes
5 – 3 votes

MAP Health Equity Advisory Group Input:
Relative priority/utility:

- Lower-resourced hospitals may have some disadvantage. Consider the inequity from a system perspective and not from the patient-perspective.
- This is a great quality measure, but not sure there is an equity component here.

Data collection issues:

- None

Calculation issues:

- None

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Unintended consequences:

- None

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.3
1 – 0 votes
2 – 1 votes
3 – 16 votes
4 – 5 votes
5 – 1 votes

Recommendation

Preliminary Analysis Recommendation:
Support for Rulemaking

Summary: What is the potential value to the program measure set?
This fully developed and specified measure addresses a critical and preventable safety event in the Medicare Promoting Interoperability Program for Hospitals. The program does not currently include a measure that addresses ORAEs and subsequent administration of naloxone in the inpatient setting. The measure was submitted for endorsement review to the Patient Safety Standing Committee, Spring Cycle 2021 and received NQF endorsement. The measure is recommended for support.

Summary: What is the potential impact of this measure on quality of care for patients?
This measure identifies hospital inpatient opioid-related adverse events (ORAEs) in which patients are administered an opioid antagonist (naloxone) within 12 hours. Opioids have been identified among the drugs most commonly associated with adverse drug events, and ORAEs may be preventable with appropriate medication management, education and training, and patient monitoring.

Section 3: Public Comments

Federation of American Hospitals
The Federation of American Hospitals (FAH) supports addressing important patient safety concerns during an inpatient stay but questions whether this measure demonstrates a sufficient performance gap to support its use in the Hospital Inpatient Quality Reporting Program. The recent submission to the National Quality Forum reported performance scores across six hospitals that ranged between 0.11 to 0.45%.

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 vendor systems and six hospitals should not be considered sufficient. Electronic clinical quality measures (eCQMs) require significant resources and time for hospitals to implement and only those eCQMs with demonstrated gaps in care should be implemented. As a result, the FAH requests that

the highest level of MAP recommendation be “Do Not Support with Potential for Mitigation.”

American Medical Association

The American Medical Association (AMA) questions whether this measure has a sufficient variation and performance gap to support its use for accountability purposes. The recent submission to the National Quality Forum reported performance scores across six hospitals that ranged between 0.11 to 0.45%. As a result, the AMA does not believe that this measure will provide meaningful data to hospitals and patients and requests that the highest level of MAP recommendation be “Do Not Support.”

Premier, Inc.

Premier supports adoption of this measure, but recommends that CMS not more forward with it until it receives endorsement. We also recommend that CMS continue to evaluate the measure as part of the IQR program before considering it for adoption into a pay-for-performance program.

American Hospital Association

The AHA agrees with the staff recommendation of Support for this measure. We appreciate the refinements that the steward made to this measure since previous versions were reviewed by the MAP. During the 2017-2018 cycle, both the Hospital Workgroup and the Coordinating Committee recommended that the measure be revised and resubmitted as there were concerns that the measure as specified at the time included patients for whom administration of naloxone was not indicative of harm—that is, administration in the operating room or patients who were given naloxone as a result of overdose in the community and inadvertently included due to the long time window. This measure addresses those concerns by excluding patients to whom naloxone was administered in the OR (these events were also found to be challenging to extract in a structured EHR field) and uses a time window of 12 hours, which would more likely exclude patients who had ingested opioids in the community and received naloxone in the hospital.

The measure received endorsement in December and has completed field testing proving it feasible, reliable and valid. These factors, as well as the importance of the topic the measure addresses, make the measure suitable for inclusion in the IQR. We ask CMS to consider whether this measure will be one of the measures required for reporting under the Promoting Interoperability Program. In the CY 2022 OPPS proposed rule, CMS requested feedback on whether another opioid-related eCQM (Concurrent Prescribing of Opioids) should continue to be required for reporting, considering that some stakeholders have suggested this requirement might be a disincentive for some appropriate clinical decisions. It is conceivable that this measure may result in similar unintended circumstances.

Intermountain Healthcare

Intermountain is supportive of adopting this measure in the Interoperability program. However we have some concerns (also noted on MUC21-084 IQR) about how the data will be collected and harmonized across workflows to avoid extensive manual work in the IQR version and divergence of the outcomes of the measure across the IQR and Interoperability measure sets. Intermountain believes there will be considerable value in the measure for improving patient care if launched in a way to avoid excessive burden and preserve integrity across data collection methodology.

MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Medicare Promoting Interoperability Program for Hospitals, Hospital-Acquired Condition Reduction Program, Hospital IQR Program, PPS-Exempt Cancer Hospital Quality Reporting Program, Long-Term Care Hospital Quality Reporting Program, Inpatient Rehabilitation Facility Quality Reporting Program, Skilled Nursing Facility Quality Reporting Program

Workgroup
Hospital

Measure Description
This measure tracks the development of new Clostridioides difficile infection among patients already admitted to healthcare facilities, using algorithmic determinations from data sources widely available in electronic health records. This measure improves on the original measure by requiring both microbiologic evidence of C. difficile in stool and evidence of antimicrobial treatment.

Numerator
Healthcare-Associated Clostridioides difficile Infection (HA-CDI):
Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.
HA-CDI 1: must meet BOTH A & B.
A) Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.
B) Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.
HA-CDI 2: must meet BOTH A & B.
A) Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.
B) Administration of oral or intravenous metronidazole within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

Numerator Exceptions
Excluding well baby-nurseries and neonatal intensive care units (NICU).

Denominator
The expected number of HA-CDI based on predictive models using facility- and patient care location data as predictors.

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Denominator Exclusions
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count
Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions
Under investigation, subject to change.

State of development
Specification

State of Development Details
The measure stewards have partnered with several research groups to evaluate HA-CDI in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing.

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Infectious disease

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1. Microbiology records of stool tests for C. difficile, typically from an EHR laboratory information system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

The HA-CDI measure requires linking relevant stool microbiological test results with applicable antimicrobial administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

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What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

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If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
MUCFIFTEEN-533: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

How will this measure be distinguished from other similar and/or competing measures?
The current NHSN measure is based on laboratory results, and C. difficile is typically diagnosed using non-culture based diagnostic tests which have wide variation in sensitivity and in rates of false positives. Creating a surveillance definition that more closely approximates the disease-state requires incorporating clinical decision-making into the measure. The updated measure includes not only the lab test for C. difficile but also the use of an antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the limited and particular therapies used for infections due to C. difficile.

How will this measure add value to the CMS program?
This new measure increases the clinical validity of original measure, and therefore more accurately reflect the presence of clinical infection and quality measurement.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

C. difficile caused 159,463 infections among hospitalized US patients in 2019. (1) Robust surveillance combined with incentives from value-based purchasing resulted in a reduction of 42% between 2015 and 2019 in acute-care hospitals. (1) Further improvements are possible, but aspects of the existing surveillance definition complicate the external reception of the measure and create unintended consequences regarding testing and treatment practices. (2, 3) These issues also challenge the ability to track trends in true infections as organizations alter their practices. Validation studies performed from 2013 -2106 by 6 different states, suggest that the negative predictive value of the metric is low at ~59% indicating that, in addition to potential manipulation of testing practices, many cases are being missed in the reporting process. (4) To address these concerns, CDC's National Healthcare Safety Network (NHSN) proposes a new measure that promotes further improvements in care for patients and reduces unintended consequences.

Creating an improved surveillance definition that more closely approximates the disease-state requires incorporating use of therapy as a proxy for clinical decision-making into the measure. To that end, this new NHSN measure includes not only the lab test for C. difficile but also the use of a specific antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the specific therapies used for infections due to C. difficile. (5)

References

1. Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI
2. Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458
3. Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf
4. Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN
5. McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

Evidence that the measure can be operationalized

There is a proven track record for CMS to obtain this data from NHSN which currently shares facility-level CDI SIRs for hospital IQR program.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

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Evidence of Performance Gap
Analysis forthcoming

Unintended Consequences
It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection. ;It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score
To be determined.

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HA-CDI event, the mean unadjusted cost is ~$50,000 (median $27,000). As an unadjusted, unmatched comparison group, hospitalizations with only a negative stool test for C. difficile had an average cost of ~$26,000 (median ~$11,000). (Unpublished data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019.

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Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
No

If yes, choose all methods that obtained clinician and/or provider input
N/A

Total Number of Clinicians/Providers Consulted
N/A

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
N/A

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

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If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs and EIP projects summer 2021.

Measure performance – Type of Score
Ratio

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Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

HA-CDI performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).
Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HA-CDI events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HA-CDI events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HA-CDI events for the facility using the negative binomial regression model.
3. Divide the number of observed HA-CDI events (1 above) by the number of expected HA-CDI events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HA-CDI events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient
case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HA-CDI events for the facility
2. Obtain the adjusted number of observed HA-CDI for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HA-CDI events
4. Obtain the expected number of HA-CDI events
5. Divide the total number of adjusted HA-CDI events (3 above) by the predicted number of HA-CDI events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable

See methods above for calculation of SIR and ARM.

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Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
Raymund Dantes
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Atlanta, GA 30333
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800-232-4636

Long-Term Measure Steward
Centers for Disease Control and Prevention

Long-Term Measure Steward Contact Information
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1600 Clifton Rd
Atlanta, GA 30333
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800-232-4636

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: No

Justification and Notes: XXXX

The Measure Under Consideration calculates the observed number of Healthcare-Associated Clostridioides difficile Infections (HA-CDI) at a health care facility, divided by the number of infections expected based on facility characteristics. For this measure to be incorporated into the Medicare Promoting Interoperability Program, the measure must both be an eCQM and be included in the Hospital Inpatient Quality Reporting Program. However, this measure does not address any of the Hospital IQR Program measurement priorities and is not an eCQM. There was historically a very similar measure included in the Hospital IQR Program, the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure (NQF 1717). However, this measure was removed beginning 2021 in order to reduce duplication with the measure in the Hospital-Acquired Condition Reduction Program (HACRP), where it is retained (CMS, 2018). Adding this measure would-re-introduce the duplication problem identified by CMS in prior reporting years.

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Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes: After several years of implementation of HA-CDI quality measures, a 48 percent decrease in reported HA-CDIs within Acute Care Hospitals was observed from 2015-2020 (Centers for Disease Control and Prevention, 2021). This indicates hospitals have successfully implemented initiatives, such as CDC's guidelines for hand hygiene, that are reducing infection rates (2002). This measure is intended to capture HA-CDI infections more precisely than the existing measure in other hospital programs by only counting those infections among inpatients that have both a positive laboratory test and evidence of an antimicrobial agent administered to the patient two days before or after the positive test result.

Does the measure address a quality challenge?
Yes/No: Yes
Justification and Notes: HA-CDI infections are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDI infections were reported to the CDC. CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures. According to NHSN reports, in 2020 the 20th percentile of performance for acute care hospitals was .182 infections observed/expected, compared to an 80th percentile performance of .762 infections observed/expected, indicating a substantial range in performance.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: No
Justification and Notes: In 2021, CMS removed a very similar measure (NQF #1717) from the Hospital IQR Program, choosing to retain the same measure in the HACRP only. Adding this measure to the Hospital IQR Program, as a precondition for including it in the Medicare Promoting Interoperability Program, would re-introduce the duplication of measurement issue identified by CMS as part of that decision.

Can the measure be feasibly reported?
Yes/No: Yes
Justification and Notes: All data elements required to calculate the measure are available in defined fields in electronic data. A similar HA-CDI measure currently implemented in other programs has been successfully submitted by thousands of acute care hospitals for several years.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: No
Justification and Notes: This measure is a specification update to an existing NQF-endorsed measure, #1717. The revised specifications have not been submitted to NQF for endorsement, and reliability and validity testing has not been finalized.

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?
Yes/No: N/A
Justification and Notes: The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test

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for CDI AND a treatment administered. This update is intended to mitigate instances where a facility or provider might be incentivized not to test for a suspected HA-CDI.

PAC/LTC Core Concept?
Yes/No: N/A
Justification: N/A

Impact Act Domain
Yes/No: N/A
Justification: N/A

Hospice High Priority Areas
Yes/No: N/A
Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.0
1 – 0 votes
2 – 0 votes
3 – 1 votes
4 – 9 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.5
1 – 0 votes

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2 – 2 votes
3 – 5 votes
4 – 10 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:

To Be Determined

Summary: What is the potential value to the program measure set?

This updated measure is intended to capture HA-CDI infections more precisely than the existing similar measure in other hospital programs by only counting those infections among inpatients that have both a positive laboratory test and evidence of treatment. MAP's interpretation of requirements of the Medicare Promoting Interoperability Program for Hospitals note that the measure must both be an eCQM and be included in the Hospital IQR Program. This measure is not an eCQM, does not address any of the current Hospital IQR Program measurement priorities, and a decision to reduce the number of measures in the program saw the removal of several infection surveillance measures including this one in 2021. This measure under consideration is conceptually very similar to the removed measure. The Coordinating Committee should focus their review of the measure solely on its specifications and appropriateness for the program. CMS will continue to review and ensure compliance with statutory requirements for the Medicare Promoting Interoperability Program for Hospitals.

Summary: What is the potential impact of this measure on quality of care for patients?

An HA-CDI infection has serious potential consequences for patients, including death. Nearly 114,000 HA-CDI were reported to the CDC in 2020. The performance of acute care hospitals on the existing HA-CDI measure shows considerable variation in performance: the 20th percentile of performance for acute care hospitals was .182 infections observed/expected, compared to an 80th percentile performance of .762 infections observed/expected. Nevertheless, this performance has improved by 48 percent over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines.

Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports the further refinements to this measure but recommends that the measure with these changes is tested and endorsed by the National Quality Form prior to implementation in this program. In addition, the Centers for Medicare and Medicaid Services must address the duplicate reporting of the measure results as these revisions are implemented in either program. The potential for misleading and/or inaccurate information must be avoided at all costs.

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As a result, the FAH requests that the highest level of MAP recommendation be “Conditional Support for Rulemaking.”

Premier, Inc.

Premier conditionally supports adoption of the measure. The refined measure improves on existing measures by requiring both evidence of an infection and treatment, which will help to exclude cases resulting from colonization and improve clinical validity of the measure. However, we are concerned that this measure is similar to the existing CDI measure and that adoption will duplicate measurement. We would encourage CMS to clarify a timeline for replacing the existing CDI measure with this refined measure. Additionally, CMS should not move forward with the measure until it has received endorsement.

America's Essential Hospitals

Below comments apply to MUC2021-098 and MUC2021-100.

The NQF-recommended decision category for these measures was “Do Not Support for Rulemaking.” The MAP Hospital Workgroup reviewed and voted on the measures under consideration based on information available at the time, as is its role. However, after the meeting and vote, in which America’s Essential Hospitals participated, members of the workgroup were informed the decision category for these measures was changed to “To Be Determined” without consultation by the workgroup, and the measures will be re-evaluated by the MAP Coordinating Committee. This deviation from the usual process is of great concern to America’s Essential Hospitals. To our knowledge, the MAP decision-making process does not permit NQF staff to make such changes and the act of doing so raises questions about the MAP process itself, both for MAP Hospital Workgroup members and the public.

America’s Essential Hospital is a longstanding member of the MAP Hospital Workgroup and a strong proponent of NQF’s role in convening a multistakeholder group to evaluate measures. However, this unilateral change in decision category disregards the decision-making process and the votes cast by the MAP Hospital Workgroup. We urge NQF to uphold the decision of the MAP Hospital Workgroup and allow the MAP Coordinating Committee to review additional information at the time of its Jan. 19 meeting to maintain the integrity of the MAP process. We also urge NQF to develop a more transparent policy moving forward outlining the limited circumstances when measure clarification is warranted after a workgroup has voted.

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MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Medicare Promoting Interoperability Program for Hospitals, Hospital-Acquired Condition Reduction Program, Hospital IQR Program, PPS-Exempt Cancer Hospital Quality Reporting Program

Workgroup
Hospital

Measure Description
This measure tracks the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in electronic health records. This measure includes many healthcare-associated infections not currently under surveillance by the Center for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN). Ongoing surveillance also requires minimal data collection burden for users.

Numerator
Observed number of Hospital-Onset Bacteremia & Fungemia (HOB) events, defined below:
Must meet Bacteremia OR Fungemia criteria (BFC), AND Antimicrobial treatment criteria (ATC).
Bacteremia OR Fungemia criteria (BFC):
Patient of any age has a recognized bacterial or fungal pathogen from a blood specimen collected on the 3rd calendar day of admission or later (where the date of admission to an inpatient location is calendar day 1). The pathogen must not be included on the NHSN common commensal list, and meet EITHER of the following criteria:

1. Pathogen identified by culture of one or more blood specimens, OR
2. Pathogen identified to the genus or species level by non-culture based microbiologic testing (NCT) methods. Note: if blood is collected for culture within 2 days before, or 1 day after the NCT disregard the result of the NCT and use only the result of the CULTURE to make a BFC determination. If no blood is collected for culture within this time period, use the result of the NCT for BFC determination.

Antimicrobial Treatment Criteria (ATC):
A patent must have been administered at least 1 dose of an intravenous or oral (including all enteral routes) antimicrobial in the window period extending 2 calendar days before and 2 calendar days after the date of blood specimen collection for BFC. The date of blood specimen collection is day 0. Furthermore, if the patient had Bacteremia, only antibiotics are eligible to meet the ATC criteria. Similarly, if the patient has Fungemia, only antifungals are eligible to meet ATC criteria. If a patient has both Bacteremia and Fungemia, then either an antibiotic or antifungal can meet the ATC criteria.

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Numerator Exceptions

1. Previous matching Present on Admission Bacteremia or Fungemia
2. If a patient meets BFC but also had a pathogen matching to the same species or genus level identified from a blood specimen by culture or NCT that was collected in the Present on Admission (POA) window, defined as hospital calendar day 2 or earlier (where calendar date of admission to an inpatient location is day 1), then this BFC is excluded from the HOB measure.
3. If multiple pathogens are identified from the same blood culture or NCT, then a match of any of those pathogens to a POA blood pathogen is sufficient to exclude the BFC from the HOB measure.
4. Previous HOB event
5. A patient with a previous HOB event is excluded from additional HOB events during the same hospital admission.

Denominator

The expected number of HOB events based on predictive models using facility- and patient care location data as predictors.

Denominator Exclusions

Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts. Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions

Under investigation, subject to change.

State of development

Specification

State of Development Details

Specification: The measure stewards have partnered with several research groups to evaluate HOB in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing:
A) Hospital-Onset Bacteremia & Fungemia Preventability Evaluation (HOPE): Two components

1. Evaluation of sources and preventability of HOB events in ~2400 adult and pediatric patients across 13 hospitals. Results expected summer/fall 2021.
2. HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes, and risk factors for HOB in Cerner Healthfacts and Premier Healthcare Databases (500 hospitals, 18,000,000 admissions). Results expected summer 2021.

B) Becton Dickinson: HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes and cost, risk factors, and surveillance feasibility for HOB in 271 hospitals, 8,000,000 admissions. Results expected summer/fall 2021.
C) Veterans Affairs: HOB definition sensitivity analysis, chart review validation, evaluation of epidemiology, surveillance feasibility in 142 hospitals, 1,700,000 admissions. Results expected summer 2021.

What is the target population of the measure?

All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Infectious disease

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Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1. Microbiology records of blood cultures and NCT, typically from an EHR laboratory information system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

The HOB measure requires linking relevant microbiological test results for blood cultures and NCT with applicable antimicrobial administration records from the medication administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

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If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

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Which measure(s) already in a program is your measure similar to and/or competing with?
MUC2019-19: "National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection Outcome Measure"
MUCFIFTEEN-532MRSA: "National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure"

How will this measure be distinguished from other similar and/or competing measures?
The HOB outcome measure collects the number of bloodstream infections that occur during hospitalization (and not present on admission) due to a broad range of pathogenic bacteria and fungi (in contrast to the narrower MRSA measure), and regardless of whether the infection was attributable to a central line or device (in contrast to the narrower CLABSI measure).

Furthermore, the inclusion of evidence of antimicrobial treatment for the HOB measure increases the clinical validity of the measure by acting as a proxy for true infections requiring treatment from the provider. This component may become more valuable as emerging non-culture based microbiologic testing (NCT) become more ubiquitous. These tests may have increased false positive signals or could detect pathogen genetic material that may not correspond to live pathogens causing an ongoing bacteremia or fungemia. Thus, requiring evidence of antimicrobial treatment serves as a proxy for the clinical interpretation of infection by the provider.

How will this measure add value to the CMS program?
The HOB outcome measure includes most to nearly all central-line associated bloodstream infections and MRSA bacteremias, and many more bloodstream infections that cause healthcare associated infections but are not currently under surveillance for quality measurement. Preliminary data suggests a substantial percentage of HOB events are preventable under current infection prevention standards, and we anticipate that use of an HOB outcome measure will encourage innovation to identify new methods for reducing these infections.

Furthermore, the HOB measure uses an algorithmic approach to determine events, thus reducing regular data collection burden and subjectivity from event determination. "HOB surveillance could inform broad measures to improve infection control in conjunction with other HAI data, potentially resulting in measurably improved patient outcomes. HOB data collection and reporting burden would likely be low given the ubiquity and functionality of current EHRs, in contrast to NHSN CLABSI and other measures that call for substantial investments of time and effort in manual reviews of healthcare records."(1)
References:
1) Dantes et al. Hospital epidemiologists' and infection preventionists' opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Multiple justification studies are underway.
An HOB measure is viewed favorably among subject matter experts and users. A survey of 89 researchers in the Society for Hospital Epidemiology of America (SHEA) Research Network found that "Among the majority of SHEA Research Network respondents, HOB is perceived as preventable, reflective of quality of care, and potentially acceptable as a publicly reported quality metric." Furthermore, "Given a choice to publicly report central-line-associated bloodstream infections (CLABSIs) and/or HOB, 57% favored reporting either HOB alone (22%) or in addition to CLABSI (35%) and 34% favored CLABSI alone. (1)
References
1) Dantes et al. Hospital epidemiologists' and infection preventionists' opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540.

Evidence that the measure can be operationalized

The HOB measure leverages sources of data, primarily microbiology and medication administration data, that are already used for many existing CDC National Healthcare Safety Network (NHSN) measures and reported to CMS on a quarterly basis.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

Interim and preliminary analysis from the HOPE study with approximately half the data collected shows approximately 41% of HOB events were considered preventable after expert review. Final results expected summer/fall 2021.

Unintended Consequences

It is possible that providers and facilities may be discouraged from ordering blood cultures or NCT among patients that are later into their hospitalization when they suspect an infection.

Outline the clinical guidelines supporting this measure

N/A

Were the guidelines graded?

N/A

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score

To be determined.

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Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?

Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HOB event, the mean unadjusted cost is ~$83,000 (median $44,000). As an unadjusted, unmatched comparison group, hospitalizations with negative blood cultures had an average cost of ~$45,000 (median $26,000). (Data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

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If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys

Total Number of Clinicians/Providers Consulted
76

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
41

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs project summer 2021

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs project summer 2021

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs project summer 2021

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Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs project summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs project summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs project summer 2021.

Measure performance – Type of Score
Ratio

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
HOB performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).
Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HOB events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HOB events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HOB events for the facility using the negative binomial regression model
3. Divide the number of observed HOB events (1 above) by the number of expected HOB events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HOB events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in

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the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HOB events for the facility
2. Obtain the adjusted number of observed HOB for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HOB events
4. Obtain the expected number of HOB events
5. Divide the total number of adjusted HOB events (3 above) by the predicted number of HOB events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable
See description of SIR and ARM above.

Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
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Long-Term Measure Steward
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Section 2: Preliminary Analysis – MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: No

Justification and Notes: This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. For this measure to be incorporated into the Medicare Promoting Interoperability Program, the measure must both be an eCQM and be included in the Hospital IQR Program. However, this measure does not address any of the Hospital IQR Program's measurement priorities and is not an eCQM. There are two measures that historically were in included in the Hospital IQR Program, whose measure result would be reflected in this proposed measure: (1) the NHSN MRSA bacteremia measure, and (2) the NHSN CLABSI measure. However, both were removed from IQR beginning in 2020, in order to reduce duplication with measures in the Hospital-Acquired Condition Reduction Program (HACRP), where they were retained. Adding this measure would-re-introduce the duplication problem identified by CMS in prior reporting years. The MAP should consider whether adding this measure into the program will lead to re-introducing duplication of measures.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: There is evidence that the HOB tracked by this outcome measure can be prevented by hospitals; one 2017 study by Dantes et al estimated that 49% of HOB infections were potentially preventable, and a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists estimated that 50% or more of HOBs could be prevented, with a variety of hospital practices identified that could reduce HOBs. In an unpublished analysis of healthcare data by the measure submitter, hospitalizations with an HOB were found to be nearly twice as expensive as those without (average cost of $83,000 compared to $45,000).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: HOB are common infections, especially relative to other infections currently measured in quality reporting programs: for example, a 2015 study by Rock et al found that HOB infections were 17 times as likely to be observed in an ICU compared to CLABSI infections. The same study concluded that a change in HOB rate has a greater power to discriminate between ICU performance than CLABSI rates. Contracting an HOB leads to a greatly increased risk of mortality, as found by Lambert et al, 2011. The developer also cites preliminary results from the HOPE study analysis in which approximately 41% of HOB events were considered preventable after expert review. The developer notes that final study results are expected summer/fall 2021. Although performance data for this measure are not yet available, a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists found that 54% agreed that the measure concept would reflect quality of care at a hospital.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: In 2020, CMS removed a suite of infection surveillance measures from the IQR program, choosing to retain them in the Hospital-Acquired Condition Reduction Program (HACRP) only. Adding this measure to the IQR program, as a precondition for including it in the Medicare Promoting

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Interoperability Program, would re-introduce the duplication of measurement issue identified by CMS as part of that decision. The MAP should consider whether adding this measure into the program will lead to re-introducing duplication of measures.

Can the measure be feasibly reported?

Yes/No: Yes
Justification and Notes: All data elements are available in defined electronic fields; no data abstraction is required.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes
Justification and Notes: The measure is specified for the appropriate care setting, level of analysis, and patient population. However, no reliability or validity testing of the measure result has been conducted, and the measure has not been reviewed for endorsement by the National Quality Forum.

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?

Yes/No: No
Justification and Notes: Although the measure has not been implemented or tested in a healthcare facility, one possible unintended consequence that the developer identified is that the measure may discourage providers and hospitals from testing patients where they suspect a bacteremia or fungemia infection.

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.8
1 – 0 votes
2 – 1 votes
3 – 1 votes
4 – 8 votes
5 – 1 votes

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MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.2
1 – 0 votes
2 – 3 votes
3 – 7 votes
4 – 7 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
To Be Determined

Summary: What is the potential value to the program measure set?
This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. MAP's interpretation of the Medicare Promoting Interoperability Program for Hospitals notes that the measure must both be an eCQM and be included in the Hospital IQR Program. This measure is not an eCQM. Although this measure does not address any of the program measurement priorities, it does correspond to the Patient Safety focus within CMS' Meaningful Measures 2.0. A 2020 decision to reduce the number of measures in IQR saw the removal of several infection surveillance measures; this Measure Under Consideration is conceptually very similar to those. The Coordinating Committee should focus their review of the measure solely on its specifications and appropriateness for the program. CMS will continue to review and ensure compliance with statutory requirements for the Medicare Promoting Interoperability Program for Hospitals.

Summary: What is the potential impact of this measure on quality of care for patients?
This Measure Under Consideration tracks a group of very common, and potentially lethal, hospital-acquired infections. Hospitalizations where these conditions were identified were nearly twice as expensive as the average hospital stay, indicating high resource utilization needed to treat these conditions. Despite the common and costly nature of these infections, studies and surveys estimate that nearly half of these infections are preventable by the hospital. Incentivizing the adoption of infection control practices that would reduce the incidence of these conditions would present a substantial benefit to both patients and the health care system.

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Section 3: Public Comments

Federation of American Hospitals

The Federation of American Hospitals (FAH) supports measures that ensure patient safety and reduction of infections for individuals receiving care during an inpatient stay but measures must be based on robust evidence and produce reliable and valid results. This measure does not currently meet any of these minimum requirements nor has it received endorsement by the National Quality Forum. As a result, the FAH requests that the highest level of MAP recommendation be "Do Not Support with Potential for Mitigation."

Premier, Inc.

Premier conditionally supports adoption of this measure. While we agree that this measure addresses some healthcare-associated infections not currently under NHSN surveillance, we are concerned that it may duplicate existing measurement under the HAC Reduction Program (e.g., CLABSI and MRSA measures). We encourage CMS to develop a strategy that ensures broader surveillance of HAIs without increasing burden on hospitals or duplication of existing efforts. Additionally, CMS should not move forward with the measure until it has received endorsement.

America's Essential Hospitals

Below comments apply to MUC2021-098 and MUC2021-100.

The NQF-recommended decision category for these measures was "Do Not Support for Rulemaking." The MAP Hospital Workgroup reviewed and voted on the measures under consideration based on information available at the time, as is its role. However, after the meeting and vote, in which America's Essential Hospitals participated, members of the workgroup were informed the decision category for these measures was changed to "To Be Determined" without consultation by the workgroup, and the measures will be re-evaluated by the MAP Coordinating Committee. This deviation from the usual process is of great concern to America's Essential Hospitals. To our knowledge, the MAP decision-making process does not permit NQF staff to make such changes and the act of doing so raises questions about the MAP process itself, both for MAP Hospital Workgroup members and the public.

America's Essential Hospital is a longstanding member of the MAP Hospital Workgroup and a strong proponent of NQF's role in convening a multistakeholder group to evaluate measures. However, this unilateral change in decision category disregards the decision-making process and the votes cast by the MAP Hospital Workgroup. We urge NQF to uphold the decision of the MAP Hospital Workgroup and allow the MAP Coordinating Committee to review additional information at the time of its Jan. 19 meeting to maintain the integrity of the MAP process. We also urge NQF to develop a more transparent policy moving forward outlining the limited circumstances when measure clarification is warranted after a workgroup has voted.

American Medical Association

The American Medical Association (AMA) is extremely concerned with the placeholder of To Be Determined (TBD) in the Initial Recommendation category of the spreadsheet. The Hospital Workgroup had robust discussion on this measure and its appropriateness for multiple programs, including the Promoting Interoperability program and they achieved a clear consensus to recommend "Do Not Support" for this measure in this program. The decision to override the votes of the Workgroup is unprecedented and we believe that it calls the integrity of the Measures Application Partnership (MAP) process into question.

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The AMA urges the National Quality Forum (NQF) staff to include the recommendation of "Do Not Support" from the Hospital Workgroup and follow existing, approved MAP processes. Specifically, if the Coordinating Committee chooses to reconsider this recommendation, they may do so. Furthermore, if the Centers for Medicare & Medicaid Services (CMS) wishes to present additional detail or background on why they believe that this measure is appropriate for the Promoting Interoperability program, opportunities for this presentation have been provided in the past and we do not see why a similar process should not be followed for this measure.

American Hospital Association

We note that the measure disposition of "TBD" included in the draft report differs from hospital workgroup's recommendation of do not support. As a general principle, the AHA believes any workgroup votes presented to the coordinating committee should reflect the workgroup's discussions, and should not be altered without the workgroup taking formal action to change the vote. At the same time, we recognize that CMS provided additional clarifying information following the workgroup meeting that merits additional consideration from the Coordinating Committee. NQF staff have indicated they will clarify the vote's disposition to the Coordinating Committee, and are working on a policy to ensure there is a transparent, consistent approach for processing clarifying information that becomes available in between the workgroup meeting and the coordinating committee. The AHA greatly appreciate the NQF team's attention to this issue, and stand ready to assist as needed.

We appreciate the CDC's work to improve the accuracy of measures assessing hospital-acquired conditions by coupling clinical information from electronic health records with lab tests. However, we urge CMS to exercise caution in adopting this measure, as the concept of a broad-based bacteremia measure carries inherent risks and trade-offs.

First, this measure of new bacteremia and fungemia infections would include nearly all CLABSIs and MRSA infections, and thus would overlap with existing measures evaluating these occurrences. CMS needs to ensure that measure sets are consistent and complementary, and during the MAP meeting representatives noted that the agency does not anticipate removing the current measures simultaneously with the adoption of this new measure. We worry that this will result in double-counting of infections or inconsistent calculation of performance across disparate measures.

A related issue with introducing a new HAC measure is the lack of baseline. Because the measure is not entirely comparable to existing HAC measures, an entirely new baseline would have to be established. This would necessitate a multi-year implementation process, further muddying the data used for the HAC program. These logistical concerns do not necessarily detract from this measure's usefulness, but we do encourage CMS to thoughtfully construct a plan and educational approach for the use of this and other HAC measures.

Finally, we are concerned that a measure assessing incidence of any bacteremia or fungemia on the NHSN common commensal list may not necessarily enhance quality improvement efforts. Given the evidence presented to the workgroup, we are not sure whether all pathogens are equally preventable, and whether this topic is the right focus for a program that has been evolving as best practices and improvement collaboratives have evolved as well. Because of these concerns, we recommend that the measure developer work more with stakeholders to analyze results of the alpha testing period as well as the potential use of this measure in future CMS programs—and this may be the far future, considering

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the lengthy implementation process likely necessary for this measure.

Association of American Medical Colleges (AAMC)

The Hospital MAP Workgroup did not support these measures (MUC2021-098 and MUC2021-100) for the Medicare Promoting Interoperability Program due to a concern that these measures are not appropriate for the program as they are not specified as electronic clinical quality measures (eCQMs). Rather, these measures use algorithmic determinations from data sources available in electronic health records (EHRs). However, post-meeting NQF staff revised these recommendations to "to be determined" after CMS urged them to read the Program's authorizing statute (the HITECH Act of 2009) as requiring only those measures in the program use certified EHR technology for reporting (and not specifically be eCQMs). While we understand there is room for debate for the Coordinating Committee in finalizing the recommendation, the AAMC is incredibly concerned with the integrity of the independent MAP process if NQF staff can unilaterally change a recommendation that met a consensus vote upon review by the Hospital MAP Workgroup. We appreciate NQF leadership's consideration of our concerns with this change to the recommendation when it was brought to their attention and support the establishment of a process in the future on how to address similar issues that may arise. Furthermore, in regards to the specific requirements for measurement set forth in the authorizing statute, the AAMC urges the Coordinating Committee to consider the requirement that measures selected should "avoid redundant or duplicative reporting otherwise required." (See Section 1848(o)(2(B)(iii) of the Social Security Act, 42 U.S.C. § 1395w-4, as amended in 2009, stating "COORDINATION OF REPORTING OF INFORMATION. —In selecting such measures, and in establishing the form and manner for reporting measures under subparagraph (A)(iii), the Secretary shall seek to avoid redundant or duplicative reporting otherwise required[.]") We believe this at least poses a question whether it is appropriate to support these measures for rulemaking in the Promoting Interoperability Program when they are also being considered for use in the IQR and Hospital Acquired Condition Reduction Programs. This is especially relevant considering the latter is a pay-for-performance program.

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MUC2021-104 Severe Obstetric Complications eCQM

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Medicare Promoting Interoperability Program for Hospitals, Hospital Inpatient Quality Reporting Program

Workgroup
Hospital

Measure Description
Proportion of patients with severe obstetric complications which occur during the inpatient delivery hospitalization.

Numerator
Inpatient hospitalizations for patients with severe obstetric complications occurring during the delivery hospitalization (not present on admission) including the following:

- Severe maternal morbidity diagnoses (see list below)
- Severe maternal morbidity procedures (see list below)
- Discharge disposition = expired
- ICU length of stay greater than 12 hours at any time during the encounter
- Serum creatinine = 2 mg/dL
- PaO2 < 60 mmHg
- Platelet count < 100 10^3/uL

Severe Maternal Morbidity Diagnoses:

- Cardiac
    - Acute heart failure
    - Acute myocardial infarction
    - Aortic aneurysm
    - Cardiac arrest/ventricular fibrillation
    - Heart failure/arrest during procedure or surgery
- Hemorrhage
    - Disseminated intravascular coagulation
    - Shock
- Renal
    - Acute renal failure
- Respiratory
    - Adult respiratory distress syndrome

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    - Pulmonary edema
- Sepsis
- Other OB
    - Air and thrombotic embolism
    - Amniotic fluid embolism
    - Eclampsia
    - Severe anesthesia complications
- Other Medical
    - Puerperal cerebrovascular disorder
    - Sickle cell disease with crisis

Severe Maternal Morbidity Procedures:

- Blood transfusion
- Conversion of cardiac rhythm
- Hysterectomy
- Temporary tracheostomy
- Ventilation

Numerator Exceptions

N/A

Denominator

Inpatient hospitalizations for patients delivering stillborn or live birth with = 20 weeks, 0 days gestation completed.

Denominator Exclusions

Inpatient hospitalizations for patients with trauma complicating childbirth diagnoses.

Denominator Exceptions

N/A

State of development

Fully Developed

State of Development Details

Alpha testing has been completed for the Severe Obstetric Complications eCQM, which consisted of virtual EHR walkthroughs with nine healthcare pilot sites consisting of 27 individual hospitals. EHR walkthroughs included site EHR experts, report writers, and clinical leads to assess feasibility of the data elements necessary to define the measure specifications. Alpha testing included assessment of clinical and documentation workflows compared to measure intent, assessment of data element availability and accuracy, and assessment of use of data standards to support the completion of the Feasibility Scorecard.

Beta testing consists of testing of the Measure Authoring Tool (MAT) specifications, including value sets, with recruited hospitals to further establish the feasibility and validity of each of the data elements as well as the validity of the outcome. In Beta Testing, we assessed the accuracy of the data extracted from the EHR using the MAT specifications by comparing the data values to values identified through medical record abstraction. Additionally, we confirmed the accuracy of the outcome through clinical medical

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record review. Beta testing was conducted with data from eight healthcare test sites and 25 hospitals using three different HER systems: Epic, Cerner, and Medictech.

Please see the attached summary documents for results:

- ePC07 Testing Summary MUC Submission 05.11.2021 Updated 10.08.2021
- SevereObstetricComplications eCQM Measure Results MUC Submission 10.08.2021

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Obstetrics/gynecology

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Electronic Clinical Data (non-EHR); Electronic Health Record

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
This measure uses electronic health record and electronic clinical data to define all components of the measure: measure denominator, measure numerator, exclusions, risk adjustment variables, and stratification variables.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Hospital inpatient acute care facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
Epc 07

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What is the endorsement status of the measure?

Never Submitted

NQF ID Number

N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?

N/A

If not exactly as endorsed, specify the locations of the differences

N/A

If not exactly as endorsed, describe the nature of the differences

N/A

If endorsed: Year of most recent CDP endorsement

N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review

2022

Submitter Comments

(Pertaining to row 087-088 above). The goal of risk adjustment is to account for patient-level factors that are clinically relevant, have strong relationships with the outcome, and are outside of the control of the reporting entity, without obscuring important quality differences. This measure risk adjusts for case mix differences among hospitals based on clinical status of the patient and other patient characteristics at the time of admission including a Housing Instability variable. In addition, this measure intends to consider stratifying measure results by race and ethnicity. Research and prevalence data have indicated considerable racial and ethnic disparities in maternal outcomes. Stratification of results by race/ethnicity will enhance interpretability of results and will provide useful and important information for hospitals seeking to improve quality outcomes for patients and for patients making decisions about care.

Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?

Yes

If eCQM, enter Measure Authoring Tool (MAT) number

1028

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?

Yes

If eCQM, does any electronic health record (EHR) system tested need to be modified?

No

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If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?

New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program.

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
No

Which measure(s) already in a program 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

How will this measure add value to the CMS program?
N/A

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Although the United States (US) is one of the most developed countries, there continues to be a staggering increase in the number of pregnant women who suffer from complications associated with Severe Maternal Morbidity (SMM). It has been found that rates of SMM are steadily increasing in the US [1]. Approximately 144 per 10,000 women hospitalized for delivery have experienced SMM, including hemorrhage, embolism, hypertension, stroke, and other serious complications [1]. Considerable racial and ethnic disparities exist; Black women and Hispanic women are at considerably higher risk for

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developing these complications and experiencing maternal mortality than are Non-Hispanic White women [2,3]. Additionally, recent maternal mortality data from 2018 reveal that 658 women died from maternal causes, resulting in a rate of 17.4 deaths per 100,000 live births, with 77% of the deaths attributed to direct obstetric causes like hemorrhage, preeclampsia, obstetric embolism, and other complications [4].

Per report from the Center for Disease Control and Prevention (CDC), the overall rate of SMM increased almost 200%, from 49.5 per 10,000 delivery hospitalizations in 1993 to 144.0 per 10,000 delivery hospitalizations in 2014 [1]. This increase has been mostly driven by blood transfusions, which increased by almost 400% in that period. Excluding blood transfusions, there has been a 22.4% increase in SMM, from 28.6 in 1993 to 35.0 in 2014 [5]. Increasing rates of SMM are resulting in increased healthcare costs and, longer hospitalization stays [6-9].

National evaluation of hospitals' performance on maternal morbidity and mortality is limited because there are currently no maternal morbidity or obstetric complications outcome measures in national reporting programs. Current quality measures related to pregnancy and maternal health proposed for or in public reporting programs are largely process measures (e.g., Maternity Care: Post-partum Follow Up and Care Coordination) and outcome measures related to delivery type (e.g., PC-01 Elective Delivery). The high maternal mortality and morbidity rates in the United States present unique opportunities for large-scale quality measurement and improvement activities. Statistics on preventability vary but suggest that a considerable proportion of maternal morbidity and mortality events could be prevented [10,11].

This measure will therefore assist in the discovery and understanding of SMM outcomes and disparities in maternal outcomes, which can lead to improvements in the safety and quality of maternal care necessary to reduce SMM and mortality rates.

1. Severe maternal morbidity in the United States. (2017) https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html
2. Leonard SA, Main EK, Scott KA, Profit J, Carmichael SL. Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology. 2019;33:30-36.
3. Petersen EE, Davis NL, Goodman D, et al. Vital signs: pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report. 2019;68(18):423.
4. 4.Hoyert DL, Miniño AM. Maternal mortality in the United States: changes in coding, publication, and data release, 2018. 2020.
5. Rates in severe morbidity indicators per 10,000 delivery hospitalization. (2020, February 10). From https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.html
6. 6.Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.
7. 7.Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology.
8. Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine.

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9. Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019.
10. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education. 2019;40(36):8.2

11. Geller SE, Rosenberg D, Cox SM, et al. The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology. 2004;191(3):939-944

Evidence that the measure can be operationalized

This measure is based on data elements that are in structured fields and extractable from the electronic health record (EHR). CMS intends to operationalize this measure as an eCQM in the acute care inpatient hospital population using data consistently captured during care. Utilizing EHR data for quality improvement and measurement efforts has several advantages compared to claims data alone, because the data tend to be clinically rich and produced in real time [12]. The Severe Obstetric Complications eCQM will help address the patient safety priority area under the Meaningful Measures 2.0 Framework.

Please see the summary documentation and Feasibility Scorecards, attached, for evidence of data source availability.

12. OPTUM. The Benefit of using both claims data and electronic medical record data in health care analysis. 2012

How is the measure expected to be reported to the program?

eCQM

Feasibility of Data Elements

All data elements are in defined fields in a combination of electronic sources.

Evidence of Performance Gap

The high maternal mortality and morbidity rates in the United States present unique opportunities for large-scale quality measurement and improvement activities. Statistics on preventability vary but suggest that a considerable proportion of maternal mortality and morbidity events could be prevented. A 2019 report from 14 maternal mortality review committees conducting a thorough review of pregnancy-related deaths determined that 65.8% of them were preventable [10]. Additionally, a study that examined preventability of pregnancy-related death, women with near-miss morbidity, and those with severe morbidity found that 40.5% of deaths, 45.5% of near miss morbidity, and 16.7% of other severe morbidities were preventable [11]. Moreover, there is also evidence that there is variability in SMM rates among hospitals. Using the CDC definition of SMM, the US median rate was 1.4% and the highest hospital rate was 12.2% [18].

Current quality measures related to pregnancy and maternal health proposed for or in public reporting programs are largely process measures (e.g., Maternity Care: Post-partum Follow Up and Care Coordination) and outcome measures related to delivery type (e.g., PC-01 Elective Delivery), but there is a lack of outcome measures in this space.

There are also numerous state agencies, private and/or non-profit organizations, and collaboratives that have spearheaded maternal health and quality improvement initiatives. For instance, the Alliance for Innovation in Maternal Health (AIM) developed evidence-based patient safety bundles to address leading causes of SMM, like obstetric hemorrhage and hypertension. The CDC Perinatal Collaboratives

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also support various state-based efforts to promote high quality maternal care. The CMQCC created the Maternal Data Center (MDC) for hospitals with Labor and Delivery units in California, Oregon, and Washington [15]. The MDC allows hospital performance regional and statewide comparisons. Overall, such quality metrics do not currently cater to a national population because there is extensive variation and timing delays in the widespread adoption and implementation of safety protocols in obstetric care across states [16,19]. Moreover, data examining the nationwide implementation of these resources are not widely available [20]. Therefore, the development of a maternal morbidity outcome measure addresses a national measurement gap that can build on learnings from existing maternal health initiatives and measures.

10. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education. 2019;40(36):8.2

11. Geller SE, Rosenberg D, Cox SM, et al. The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology. 2004;191(3):939-944

12. OPTUM. The Benefit of using both claims data and electronic medical record data in health care analysis. 2012

13. Hamilton BE, Martin JA, Osterman MJK. Births: Provisional data for 2019. Vital Statistics Rapid Release; no 8. Hyattsville, MD: National Center for Health Statistics. May 2020. Available from: https://www.cdc.gov/nchs/data/ vsrr/vsrr-8-508.pdf.

14. CDC. User guide to the 2017 fetal death public use file. Atlanta, GA: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2017. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/ Dataset_Documentation/DVS/fetaldeath/2017FetalUserGuide.pdf

15. California Maternal Quality Care Collaborative (CMQCC). Who We Are. Retrieved from https://www.cmqcc.org/who-we-are

16. Main EK. Reducing maternal mortality and severe maternal morbidity through state-based quality improvement initiatives. Clinical obstetrics and gynecology. 2018;61(2):319-331.

17. American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine. (2016, September 01). Severe maternal morbidity: Screening and review. American Journal of Obstetrics & Gynecology, 215(3), B17-B22. http://dx.doi.org/https://doi.org/10.1016/j.ajog.2016.07.050'

18. Deadly Deliveries: Childbirth complication rates at maternity hospitals. https://www.usatoday.com/maternal-mortality-harm-hospital-database/

19. Lenfant C. Clinical research to clinical practice—lost in translation? New England Journal of Medicine. 2003;349(9):868-874.

20. Maher-Griffiths C. Maternal Quality Outcomes and Cost. Critical Care Nursing Clinics. 2019;31(2):177-193.

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Unintended Consequences

Measuring obstetric complication outcomes based on EHR data may cause a shift in a hospital's resources to support EHR data extraction and reporting, and away from other functions. Also, although the measure numerator definition is broad, hospitals may potentially focus on complications captured in the measure, while dismissing other complications not currently measured but that are important, as well.

Outline the clinical guidelines supporting this measure

The American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM) recommend identifying potential cases of severe maternal morbidity for further review, with a focus on outcomes and complications, and consider this an important step toward promoting safe obstetric care [17].

This measure can lead to better quality of care for pregnant women. Severe maternal morbidity events are often avoidable through appropriate care, monitoring, and early intervention. Implementation of this measure would identify patients who experience severe maternal morbidity and mortality in the hospital inpatient setting and incentivize hospitals to implement clinical workflows that facilitate evidence-based management to reduce the likelihood of these events. This measure may result in fewer patients experiencing adverse obstetric events, and thereby improve patient outcomes and experience, prevent longer lengths of stay, lower medical costs, and decrease patient mortality.

17. American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine. (2016, September 01). Severe maternal morbidity: Screening and review. American Journal of Obstetrics & Gynecology, 215(3), B17-B22. http://dx.doi.org/https://doi.org/10.1016/j.ajog.2016.07.050'

Were the guidelines graded?

No

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

We Intend to include deliveries performed in acute care inpatient settings nationally. The CDC estimated 3,745,540 live births in the United States in 2019 [13]. In 2017, approximately 23,000 fetal deaths (stillbirths) were reported in the United States [14]. This measure intends to include both live and still births.

13. Hamilton BE, Martin JA, Osterman MJK. Births: Provisional data for 2019. Vital Statistics Rapid Release; no 8. Hyattsville, MD: National Center for Health Statistics. May 2020. Available from: https://www.cdc.gov/nchs/data/ vsrr/vsrr-8-508.pdf.

14. CDC. User guide to the 2017 fetal death public use file. Atlanta, GA: US Department of Health and Human Services, CDC, National Center for Health Statistics; 2017. ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/ Dataset_Documentation/DVS/fetaldeath/2017FetalUserGuide.pdf

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Estimate of Annual Improvement in Measure Score

Until this measure is implemented, it is challenging to estimate annual improvement in absolute terms. However, research has indicated many pregnancy related deaths and morbidity events are avoidable. A 2019 report from 14 maternal mortality review committees conducting a thorough review of pregnancy-related deaths determined that 65.8% of them were preventable [10]. Additionally, a study that examined preventability of pregnancy-related death, women with near-miss morbidity, and those with severe morbidity found that 40.5% of deaths, 45.5% of near miss morbidity, and 16.7% of other severe morbidities were preventable [11].

Additionally, several initiatives have shown promise in reducing maternal morbidity events. For example, since the inception of the California Maternal Quality Care Collaborative (CMQCC), focused on metrics and toolkits to improve maternal outcomes, the maternal mortality rate in California has declined by 55% between 2006 and 2013 [15]. The CMQCC obstetric hemorrhage collaborative resulted in a 20.8% reduction in SMM in California hospitals compared with the 1.2% reduction in SMM among nonparticipating hospitals [16].

10. Davis NL, Smoots AN, Goodman DA. Pregnancy-Related Deaths: Data from 14 US Maternal Mortality Review Committees. Education. 2019;40(36):8.2

11. Geller SE, Rosenberg D, Cox SM, et al. The continuum of maternal morbidity and mortality: factors associated with severity. American journal of obstetrics and gynecology. 2004;191(3):939-944

12. California Maternal Quality Care Collaborative (CMQCC). Who We Are. Retrieved from https://www.cmqcc.org/who-we-are

13. Main EK. Reducing maternal mortality and severe maternal morbidity through state-based quality improvement initiatives. Clinical obstetrics and gynecology. 2018;61(2):319-331.

Type of Evidence to Support the Measure

Clinical Guidelines; Other: Clinical expertise, including TEP, technical advisory panel, patient work group, and clinical consultants

Is the measure risk adjusted, stratified, or both?

Risk adjusted; Stratified

Are social determinants of health built into the risk adjustment model?

Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event

The costs associated with delivery complications are shown to be high. Investigators evaluating costs for women with a live inpatient birth in 2013 calculated a 37% increase in delivery hospitalization costs for women experiencing severe maternal morbidity (SMM) over those without SMM among commercially insured women ($20,380 versus $14,840), and a 47% increase in delivery costs for women experiencing SMM over those without SMM among women insured with Medicaid ($10,134 versus $6,894) [5]. The differential in costs was even higher in two studies using the Agency for Healthcare Research and Quality's (AHRQ's) Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample. These

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studies, one using 2011 to 2012 data [6] and the other using 2012 to 2014 data [7], calculated average risk-adjusted hospital costs (not including physician costs) for SMM during delivery hospitalizations at over two times greater for patients with any SMM compared to patients with no SMM, 5.5 times the cost if the patient had two or more SMM events [7], and over 10 times the cost with five or more SMM events [6]. Costs are incurred due to the treatment required by SMM events and the impact on hospital lengths of stay; Premier's Bundle of Joy™ Report (2019) found that women with SMM delivering vaginally have hospital stays that are 70% longer than women with vaginal deliveries experiencing no SMM, and costs that are almost 80 percent higher [9].

1. Severe maternal morbidity in the United States. (2017) https://www.cdc.gov/reproductivehealth/maternalinfanthealth/severematernalmorbidity.html
2. Leonard SA, Main EK, Scott KA, Profit J, Carmichael SL. Racial and ethnic disparities in severe maternal morbidity prevalence and trends. Annals of epidemiology. 2019;33:30-36.
3. Petersen EE, Davis NL, Goodman D, et al. Vital signs: pregnancy-related deaths, United States, 2011–2015, and strategies for prevention, 13 states, 2013–2017. Morbidity and Mortality Weekly Report. 2019;68(18):423.
4. 4.Hoyert DL, Miniño AM. Maternal mortality in the United States: changes in coding, publication, and data release, 2018. 2020.
5. Rates in severe morbidity indicators per 10,000 delivery hospitalization. (2020, February 10). From https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.html
6. 6.Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.
7. 7.Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology.
8. Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine.
9. Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019.

Cost Avoided Annually by Medicare/Provider

Unable to determine.

Source of Estimate

Cost estimates are referenced from the following source(s):

Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.

Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology. 2018;35(13):1287-1296

Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine. 2020;173(11_Supplement): S59-S62
Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019

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Year of Cost Literature Cited

Cost estimates are from all U.S. delivery hospitalizations occurring from 2011-2012 [6]; live inpatient births from calendar year 2013 [5]; delivery hospitalizations from 2012 to 2014 [7]; and deliveries for women from 2008 through 2018 [9].

5. Rates in severe morbidity indicators per 10,000 delivery hospitalization. (2020, February 10). From https://www.cdc.gov/reproductivehealth/maternalinfanthealth/smm/rates-severe-morbidity-indicator.html

6.Vesco KK, Ferrante S, Chen Y, Rhodes T, Black CM, Allen-Ramey F. Costs of Severe Maternal Morbidity During Pregnancy in US Commercially Insured and Medicaid Populations: An Observational Study. Maternal and Child Health Journal. 2020;24(1):30-38.

7.Chen H-Y, Chauhan SP, Blackwell SC. Severe maternal morbidity and hospital cost among hospitalized deliveries in the United States. American journal of perinatology.

8. Lin C-CC, Hirai AH, Li R, Kuklina EV, Fisher SK. Rural–urban differences in delivery hospitalization costs by severe maternal morbidity status. Annals of Internal Medicine.

9. Premier Inc. Report 2: The Added Cost of Complications During and After Delivery. 2019.

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?

Yes

If yes, choose all methods of obtaining patient/caregiver information

Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives; Working groups

How many times and at what phase(s) of measure development was the patient/caregiver engaged?

Patient/caregiver representatives were engaged a total of four times to date, during measure conceptualization and following initial Beta testing. Patient/caregiver representatives provided valuable input on measurement goals, initial measure specification, and outcome and risk adjustment considerations. We intend to engage patient/caregiver representatives one to three additional times for presentation of final measures results and finalization of measure specifications.

Total Number of Patients and/or Caregivers Consulted

10

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups

1:2

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions

10

Burden for Patient: Does the measure require survey data from the patient?

No

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If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Working groups; Standard TEP

Total Number of Clinicians/Providers Consulted
13

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
13

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
9 consisting of 27 individual hospitals completed an EHR walkthrough to evaluate provider workflow and are included in the feasibility analysis.

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
77

Measure Testing Details

Reliability Testing Interpretation of Results
Overall, the study revealed the measure to have excellent data element agreement.

Measure score reliability results with signal-to-noise testing indicated excellent reliability.

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See attached summary document for detailed results.

Type of Reliability Testing

Measure Score Reliability

Reliability Testing: Type of Testing Analysis

Signal to Noise; IRR (Inter-rater reliability)

Reliability Testing Sample Size

Data element reliability testing has been completed for 15 individual hospitals. This includes 1 system of 10 hospitals and 5 individual hospitals. We reviewed 30-36 charts at each of the individual hospitals and 3-4 charts for each hospital in the system (6 test sites).

Measure score reliability testing was conducted with data from 25 hospitals. This includes 1 health system with 10 hospitals, 1 health system with 9 hospitals, and 6 individual hospitals (8 test sites).

Reliability Testing Statistical Result

Percent agreement for the data element reliability and signal-to-noise ratio was used to test measure score reliability.

Overall, the data element agreement rate for all six sites was 90.4%.

Signal-to-noise reliability was conducted for two outcomes. Signal-to-noise reliability results for Any Severe Obstetric Complications ranged from 0.982-0.997 with a mean of 0.99 (0.005 SD). Signal-to-noise reliability results for Severe Obstetric Complications Excluding Blood Transfusion Only Cases ranged from 0.916 -0.983 with a mean of 0.95 (0.023 SD).

See attached summary documents for detailed results.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?

Yes

If yes, specify the number of cases and the percentage of providers

30-36 sampled cases per pilot site (30-36 charts at each of the individual hospitals and 3-4 charts for each hospital in the system). 100% of the pilot sites met the minimum denominator requirement.

Type of Validity Testing

Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis

Correlation; Gold Standard Comparison; Other: Gold standard comparison and face validity will be assessed at the completion of testing.

Validity Testing Sample Size

Validity testing has been completed for 15 individual hospitals. This includes 1 system of 10 hospitals and 5 individual hospitals. 30-36 charts were reviewed at each of the individual hospitals and 3-4 charts for each hospital in the system.

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Validity Testing Statistical Result
Overall, the data element agreement rate for all 3 sites was 90.4%.

For measure score validity we calculated positive predictive value (PPV), as well as sensitivity, specificity, and negative predictive value (NPV), and kappa scores. The PPV over 6 test sites (with 15 hospitals) was very high at 94.74%. Sensitivity overall was 100%, specificity was 90.48%, and NPV was 100%. The overall agreement rate was 91.2% with a kappa score .881.

See attached summary documents for detailed results.

Validity Testing Interpretation of Results
The overall data element agreement rate indicates excellent agreement.

Measure score validity testing indicates high positive and negative predictive value, as well as high sensitivity and specificity, and excellent measure agreement.

See attached summary document for detailed results.

Measure performance – Type of Score
Other: We also intend to consider displaying as rate per 10,000 deliveries

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
See attached summary document for detailed results.

Benchmark, if applicable

N/A

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The Joint Commission

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Section 2: Preliminary Analysis – MUC2021-104 Severe Obstetric Complications eCQM

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes

Justification and Notes: This measure addresses the CMS Meaningful Measures area of patient safety. As an eCQM, this measure also supports the Medicare and Medicaid Promoting Interoperability Program's goal to promote quality measurement reporting through certified electronic health record technology. If included, this would be the only measure within the Promoting Interoperability program to address maternal health.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes

Justification and Notes: This measure is an outcome measure assessing the proportion of patients with severe obstetric complications during an inpatient delivery hospitalization. The overall rate of severe maternal morbidity (SMM) was 139.7 per 10,000 deliveries in the U.S. between 2016 and 2017 (Brown et al., 2020). One population-based cohort study also found a higher risk of infant death among live births with SMM compared to live births without SMM (relative risk = 2.93) (Aoyama et al., 2020)

Does the measure address a quality challenge?
Yes/No: Yes

Justification and Notes: Severe maternal morbidity (SMM) refers to unexpected outcomes of labor and delivery with severe consequences to a woman's health (Centers for Disease Control and Prevention, 2021). In the U.S., SMM rates have increased from 49.5 to 139.7 per 10,000 deliveries in the U.S. from 1993 to 2017 (CDC, 2021; Brown et al., 2020). SMM rates are also elevated in minority populations (225.7 vs. 104.7 per 10,000 deliveries in non-Hispanic Black individuals vs. non-Hispanic White individuals) (Brown et al., 2020). A case-control study of pregnancy-related deaths found

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that 40.5% of deaths, 45.5% of near-miss morbidities, and 16.7% of other severe morbidities were preventable (Geller et al, 2004).

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: The Promoting Interoperability program does not contain any measures related to maternal health. As part of the developer submission, the developer noted that current maternal health measures used in public reporting are largely process measures or outcome measures related to delivery type, but there are no measures directly addressing morbidity and obstetric complications. If this outcome eCQM is included in CMS programs, alignment across programs would be fulfilled as all eCQMs used in Hospital IQR are also reportable as part of Promoting Interoperability.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The developer shared that this measure is an eCQM that utilizes data elements in structured fields extractable from the electronic health record and consistently captured during care. The measure was alpha tested with nine healthcare pilot sites consisting of 27 individual hospitals and received an average feasibility rating of 98%.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: Yes

Justification and Notes: The proposed measure is specified at the facility level and is intended to be used in the hospital inpatient acute care setting, which aligns with the proposed program (Promoting Interoperability). This measure has not been submitted for NQF endorsement but has been tested for reliability and validity in nine pilot sites to date with sufficient measure outcome agreement (91.2%, kappa score 0.881) and a data element agreement rate of 90.4%.

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?

Yes/No: No

Justification and Notes: The measure is new and is not currently being used. The developer identified the following potential unintended consequences with the deployment of the measure. Specifically, measuring complications based on EHR data may cause hospitals to shift reports from other QI functions to EHR data extraction and reporting. Further, while the measure numerator is broad, hospitals may potentially focus on complications captured in the measure, while dismissing other complications not currently measured but that are important, as well.

PAC/LTC Core Concept?

Yes/No: N/A

Justification: N/A

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Impact Act Domain

Yes/No: N/A

Justification: N/A

Hospice High Priority Areas

Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- None

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 votes
2 – 0 votes
3 – 0 votes
4 – 10 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- This measure is essential for reducing disparities in thinking about ways to stratify by certain subpopulations
- There needs to be appropriate access to care to prevent/address these complications and not clear whether this measure will help elucidate these access issues

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- None

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Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 4.4
1 – 0 votes
2 – 0 votes
3 – 0 votes
4 – 12 votes
5 – 7 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This newly developed measure is an outcome eCQM addressing the Meaningful Measures area of patient safety. As an eCQM, the measure promotes meaningful use of certified electronic health record technology. If included, this measure would be the only outcome measure in the Promoting Interoperability program that addresses maternal health and obstetric complications. MAP did raise concerns about the sample size for testing of the measure.

Summary: What is the potential impact of this measure on quality of care for patients?
Severe maternal morbidity (SMM) rates have increased from 49.5 to 139.7 per 10,000 deliveries in the U.S. from 1993 to 2017, and racial disparities in SMM persist (225.7 vs. 104.7 per 10,000 deliveries in non-Hispanic Black individuals vs. non-Hispanic White individuals) (CDC, 2021; Brown et al., 2020). Complications are also associated with higher risk of infant death (Aoyama et al., 2020). However, an estimated 40.5% of pregnancy-related deaths, 45.5% of near-miss morbidities, and 16.7% of other severe morbidities are preventable (Geller et al, 2004).

This measure collects data on severe obstetric complications and patient outcomes in order to inform quality improvement efforts in maternal care. Conditional support for rulemaking is contingent on successful completion of measure testing and NQF endorsement.

Section 3: Public Comments

Society for Maternal-Fetal Medicine
The measure specifications were shared with the members of the Patient Safety and Quality Committee of the Society for Maternal-Fetal Medicine. Four physicians responded with these concerns:

Doctor-1 A few things…and I should preface this by saying that this is not a reaction to it based on a resistance to measuring SMM.

5. It does seem like some careful thought should be given to the name. These are sometimes complications that are not the fault of the patient or the healthcare system…they happen. Acute heart failure (cardiomyopathy of pregnancy), ruptured aortic aneurysms (for people who have undiagnosed aneurysms), amniotic fluid embolism…these are just a few examples. The reason I

bring this up is because agencies like Leapfrog and USNWR will jump on this and rate hospitals against each other against this metric without actually thinking that a good number of the things in this are not measures of the quality of care. Instead of using the word complications, which generally points at mishaps and misadventures when the general public reads it, they should come up with a more nuanced term that gives a sense that these are a general set of morbidities more than anything.

6. It is an extraordinarily complicated eCQM. Is this platelet count of <100 in someone who was admitted with a normal one? Same with SCr 2 or more? Is this a ruptured aortic aneurysm or is it just the diagnosis being in a chart? Was it an indicated hysterectomy for accreta or one that happened because of atony and delayed response to PPH? In the end, a complicated eCQM like this will require a deep manual review before the data submission, which generally negates the attempt at creating a good eCQM.
7. Generally, coding for maternal medical complications is not done as thoroughly by hospitals as it is done for other conditions, for various reasons. This will be a major adjustment for hospitals. Not saying that an adjustment may not be necessary, but the group might not understand that there is a gap in this that exists right now specifically in maternal coding.
8. It is also very biased against the hospitals that get referred the most complicated patients. Platelets <100, SCr >2, hysterectomies (in accrete patients)…those patients are risked into hospitals that are rated higher levels of maternal care. If Levels of Maternal Care work, higher levels will have higher scores for the most part.

Doctor-2

A few additional... For the top bunch of criteria...some smaller hospitals use ICU for closer surveillance to have enhanced observation and we need to be careful about disincentivizing this.

ICU admissions should be triggers for review for preventability but not a quality metric in and of themselves.

We should continue to support the prior ACOG/SMFM position (Obstetric Care Consensus) that SMM alone should not be used as a quality metric for all of the reasons that Doctor-1 outlined, as well as those outlined in the original publication. Standardized triggers (ICU admission, 4 or more units transfusion) should prompt reviews for preventability.

I feel pretty strongly that transfusion of 1 unit of blood is not a severe obstetric complication and continues to be a main driver of SMM...think we should strongly push back on equating a unit of RBC transfusion with AFE, cardiac arrest, etc.

Doctor-3

The measure outlined represents a very slippery slope, one that I fear may lead to potential reimbursement repercussions, certification withdrawals / awards, and creation of even greater hospital inequity, etc. Although the methodology used by USNWR and other organizations like LeapFrog leave much to be desired, they by and large dont have the support of the medical community. There are many factors that play a role in a patient's decision making process about which hospital to give birth in besides rankings, and by creating a medical standard, we will in essence create a grading system for all hospitals that will have repercussions whether foreseeable or not. In addition, as the metrics stand in

their current form below, they definitely favor hospitals that never deal with a complicated patient population. Although it specifies “severe obstetric complications which occur during the inpatient delivery hospitalization”, it is very hard to control for a patient that presents with an accreta and receives MTP and spends time in the ICU: an accreta center would be punished, because most accretas do not “present in DIC”. Similarly for those hospitals that deal with maternal cardiac lesions, bleeding disorders, etc. would be punished.

Doctor-4

Two questions that these metrics should attempt to answer. #1 do low risk patients have good outcomes at a given institution. #2 do high risk patients have lower complications at a given institution. I think these two questions should be clearly distinguished from each other and the metric for each are different.

Rationale for #1: most obstetric patients are low risk. Within a given community, low risk patients usually have numerous choices when it comes to obstetric care providers and institutions for obstetric care. The dynamic nature of community obstetric care provide some degree of random variation within regional systems to provide comparison of outcomes. In this setting, I would propose quality metric where the numerator can be SMM but the denominator should be all uncomplicated pregnancies (18-35yo first pregnancy without any medical or fetal complications). In order to minimize statistical clustering phenomenon the SMM may need to be time averaged over a periods of a couple years, especially for small volume hospitals.

Rationale for #2: high risk patients are often referred to regional referral centers. Referral centers generally have large catchment areas. As a result of the geographic limitations, population demographic characteristics tend to vary more between these referral centers, as would the complications being managed. As an example: racial/ethnic variations could mean some regions see more eclampsia, where as other regions see more HELLP, or some regions have higher diabetes or chronic hypertension etc. In my opinion, quality metrics can still be used for these institutions but rather than comparing between institutions, it should be used to identify areas of improvement and gauge efficacy of these projects. One could use various metrics, but I think a possible manageable option would be to use SMM as the numerator divided by the total of chronic hypertension and pregestational diabetes as these are the two most common medical complications and pretty much every population data collect these information, which have become more and more reliable over the years.

Finally, I also share the same concern with that the use of some severe and rare outcomes as the numerator would not reflect the general quality of obstetric care. While some of these outcomes may be preventable, otherwise are purely random. That’s why I think it’s important to push for a time averaged numerator to iron those out.

2020 Mom

On behalf of 2020 Mom, we appreciate the leadership of the Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum (NQF) in advancing quality of medical care and prioritizing value-based payment, and we thank you for this comment opportunity. 2020 Mom is a national nonprofit that aims to close the gaps in maternal mental healthcare. We believe that as the nation continues to grapple with a maternal morbidity and mortality crisis, we must ensure that

maternal mental health is also prioritized, as suicide and overdose are leading causes of death in the first year postpartum.

In 2019, two perinatal depression measures became available for reporting by commercial and Medicaid health insurance plans: the Prenatal Depression Screening and Follow-Up HEDIS and the Postpartum Depression Screening and Follow-Up HEDIS. We are grateful for these measures, as they will help ensure that providers screen for depression during the prenatal/postpartum period. Unfortunately, data is still not available on these quality measures. We must monitor screening and follow-up rates, per both measures, and as utilization of the measures continues, we must ensure that we can track any correlation between screening/follow-up on positive screen and receipt of treatment services/reduction in symptomatology.

While maternal mental health is not one of the measures under consideration this year, we urge CMS and NQF to maintain focus on this issue through ongoing guidance to providers on the Prenatal Depression Screening and Follow-Up HEDIS and the Postpartum Depression Screening and Follow-Up HEDIS. Additionally, where applicable, in any maternal morbidity measures, maternal mental health (i.e., perinatal depression, perinatal anxiety, perinatal obsessive-compulsive disorder, etc.) should be incorporated. For example, in MUC2021-104, which focuses on Severe Obstetric Complications, psychosis--which can onset in the immediate postpartum--should be considered.

We appreciate your ongoing commitment to maternal health, and look forward to working together on ensuring that maternal mental health measures are utilized and reported on.

Mom Congress

On behalf Mom Congress , we appreciate the leadership of the Centers for Medicare and Medicaid Services (CMS) and the National Quality Forum (NQF) in advancing quality of medical care and prioritizing value-based payment. Mom Congress is the policy organization for moms in the U.S. – a membership organization that is addressing the most pressing policy issues of motherhood including what we call the “motherload” (the stress that U.S. mothers carry, at higher rates than other developed countries). Our top priorities are maternal mortality, maternal mental health, Black & Indigenous maternal health, and paid family leave and affordable childcare. Considering our commitment to reducing maternal deaths, we appreciate MUC2021-104, which focuses on Severe Obstetric Complications. We support the measure, as it will measure severe maternal morbidity diagnoses and severe maternal morbidity procedures.

Federation of American Hospitals

The Federation of American Hospitals (FAH) strongly supports efforts to address pregnancy-related morbidity and mortality and we appreciate the Centers for Medicare and Medicaid Services (CMS) putting forward an outcome measure that specifically addresses this issue. On review of the materials released for public comment by CMS on November 19, 2021, it appears that an exclusion for patients diagnoses with Covid-19 is under consideration and the FAH strongly encourages CMS to add this exclusion in light of the public health emergency and to submit the measure to the National Quality Forum for endorsement.

In addition, while we encourage CMS to further test this electronic clinical quality measure (eCQM) 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, we are encouraged to see the number of hospitals and vendor systems used (based on the measure methodology report released for public comment). As a result, the FAH recommends that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

American Medical Association

The American Medical Association (AMA) remains committed to addressing inequity and decreasing maternal morbidity and mortality and we believe that this measure in addition to initiatives such as the Centers for Disease Control and Prevention (CDC) Alliance for Innovation on Maternal Health (AIM) bundles will drive improvements in maternal complications and death. Based on the materials released for public comment by the Centers for Medicare and Medicaid Services (CMS) on November 19, 2021, an exclusion for patients diagnosed with Covid-19 is under consideration and the AMA strongly encourages its addition to CMS. We also ask that the MAP and the NQF Standing Committee consider whether inclusion of some of the risk factors, specifically severe and other preeclampsia and obstetric VTE, are appropriate since their inclusion could mask potentially avoidable severe maternal morbidity. The AMA recommends that the highest level of MAP recommendation be "Conditional Support for Rulemaking."

American College of Obstetrician Gynecologists (ACOG)

ACOG appreciates the emphasis CMS and CORE are placing on improving maternal health outcomes and preventing adverse health outcomes. The U.S. is experiencing a maternal mortality crisis and is the only developed country with a rising maternal death rate. Equally, severe maternal morbidity (SMM) is rising in the U.S. Identifying SMM is important for preventing injuries that lead to mortality and for highlighting opportunities to avoid repeat injuries. Therefore, the creation of measures around SMM, including the Severe Obstetric Complications eCQM, is critical to improving quality of care of patients. This new measure tackles the issue of SMM by utilizing an outcome based on the Centers for Disease Control and Prevention (CDC) definition of SMM, which includes 21 indicators of SMM. Many of these indicators are commonly utilized and recognized components to identifying SMM and are reflected in the 2021 Alliance for Innovation on Maternal Health's (AIM) SMM Codes List . The current measure documentation references the 2019 AIM SMM Codes List and it is recommended to update the reference to the most current version of the AIM SMM Codes List. ACOG has not officially endorsed or created a single, comprehensive definition of SMM. This is relevant as ACOG's 2016 Obstetric Care Consensus on Severe Maternal Morbidity: Screening and Review (reaffirmed in 2021) specifically indicates that transfusions of four or more units of blood should not be included as indicator of SMM as it is typically indicative of a preexisting condition not related to pregnancy. Blood transfusions are included as an indicator of SMM as part of the numerator of this measure. While the risk adjustment component of the measure includes bleeding disorders, there should be consideration of including a specific numerator exclusion for transfusions of four or more units of blood to ensure that appropriate SMM identification is achieved without penalizing providers for non-pregnancy related disorders. This measure has the potential to useful and meaningful to patients, especially in conjunction with the recently instituted Maternal Morbidity Structural Measure in the Inpatient Prospective Payment System (IPPS) final rule focused on the implementation of quality improvement patient safety bundles through perinatal quality collaboratives. Institutions should be striving to develop and implement measures that focus on tackling issues surrounding maternal morbidity and mortality, similar to these current efforts.

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The measure specifications should be available to patients in clear language and appropriately include explanations for conditions that are captured in the measure.

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Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program (PCHQR)

MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program

Prospective Payment System (PPS)-Exempt Cancer Hospital Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Medicare Promoting Interoperability Program for Hospitals, Hospital IQR Program, Long-Term Care Hospital Quality Reporting Program, Inpatient Rehabilitation Facility Quality Reporting Program, Skilled Nursing Facility Quality Reporting Program

Workgroup

Hospital

Measure Description

This measure tracks the development of new Clostridioides difficile infection among patients already admitted to healthcare facilities, using algorithmic determinations from data sources widely available in electronic health records. This measure improves on the original measure by requiring both microbiologic evidence of C. difficile in stool and evidence of antimicrobial treatment.

Numerator

Healthcare-Associated Clostridioides difficile Infection (HA-CDI):
Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.
HA-CDI 1: must meet BOTH A & B.
A) Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.
B) Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.
HA-CDI 2: must meet BOTH A & B.
A) Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.
B) Administration of oral or intravenous metronidazole within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

Numerator Exceptions

Excluding well baby-nurseries and neonatal intensive care units (NICU).

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Denominator
The expected number of HA-CDI based on predictive models using facility- and patient care location data as predictors.

Denominator Exclusions
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count
Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions
Under investigation, subject to change.

State of development
Specification

State of Development Details
The measure stewards have partnered with several research groups to evaluate HA-CDI in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing.

What is the target population of the measure?
All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Infectious disease

Measure Type
Outcome

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims);Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources

1. Microbiology records of stool tests for C. difficile, typically from an EHR laboratory information system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

The HA-CDI measure requires linking relevant stool microbiological test results with applicable antimicrobial administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

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In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

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If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
MUCFIFTEEN-533: National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Clostridium difficile Infection (CDI) Outcome Measure

How will this measure be distinguished from other similar and/or competing measures?
The current NHSN measure is based on laboratory results, and C. difficile is typically diagnosed using non-culture based diagnostic tests which have wide variation in sensitivity and in rates of false positives. Creating a surveillance definition that more closely approximates the disease-state requires incorporating clinical decision-making into the measure. The updated measure includes not only the lab test for C. difficile but also the use of an antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the limited and particular therapies used for infections due to C. difficile.

How will this measure add value to the CMS program?
This new measure increases the clinical validity of original measure, and therefore more accurately reflect the presence of clinical infection and quality measurement.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

C. difficile caused 159,463 infections among hospitalized US patients in 2019. (1) Robust surveillance combined with incentives from value-based purchasing resulted in a reduction of 42% between 2015 and 2019 in acute-care hospitals. (1) Further improvements are possible, but aspects of the existing surveillance definition complicate the external reception of the measure and create unintended consequences regarding testing and treatment practices. (2, 3) These issues also challenge the ability to track trends in true infections as organizations alter their practices. Validation studies performed from 2013 -2106 by 6 different states, suggest that the negative predictive value of the metric is low at ~59% indicating that, in addition to potential manipulation of testing practices, many cases are being missed in the reporting process. (4) To address these concerns, CDC's National Healthcare Safety Network (NHSN) proposes a new measure that promotes further improvements in care for patients and reduces unintended consequences.

Creating an improved surveillance definition that more closely approximates the disease-state requires incorporating use of therapy as a proxy for clinical decision-making into the measure. To that end, this new NHSN measure includes not only the lab test for C. difficile but also the use of a specific antimicrobial agent or other therapy as part of the definition. In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the specific therapies used for infections due to C. difficile. (5)

References

1. Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI
2. Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458
3. Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf
4. Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN
5. McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

Evidence that the measure can be operationalized

There is a proven track record for CMS to obtain this data from NHSN which currently shares facility-level CDI SIRs for hospital IQR program.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

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Evidence of Performance Gap
Analysis forthcoming

Unintended Consequences
It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection. ;It is possible that providers and facilities may be discouraged from ordering C. difficile stool tests among patients that are later into their hospitalization when they suspect a C. difficile infection.

Outline the clinical guidelines supporting this measure
N/A

Were the guidelines graded?
N/A

If yes, who graded the guidelines?
N/A

If yes, what was the grade?
N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score
To be determined.

Type of Evidence to Support the Measure
Empirical data

Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HA-CDI event, the mean unadjusted cost is ~$50,000 (median $27,000). As an unadjusted, unmatched comparison group, hospitalizations with only a negative stool test for C. difficile had an average cost of ~$26,000 (median ~$11,000). (Unpublished data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019.

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Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
No

If yes, choose all methods that obtained clinician and/or provider input
N/A

Total Number of Clinicians/Providers Consulted
N/A

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
N/A

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

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If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs and EIP projects summer 2021.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs and EIP projects summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs and EIP projects summer 2021.

Measure performance – Type of Score
Ratio

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Measure Performance Score Interpretation

Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have

HA-CDI performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).

Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HA-CDI events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HA-CDI events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HA-CDI events for the facility using the negative binomial regression model.
3. Divide the number of observed HA-CDI events (1 above) by the number of expected HA-CDI events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HA-CDI events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient

case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HA-CDI events for the facility
2. Obtain the adjusted number of observed HA-CDI for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HA-CDI events
4. Obtain the expected number of HA-CDI events
5. Divide the total number of adjusted HA-CDI events (3 above) by the predicted number of HA-CDI events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable

See methods above for calculation of SIR and ARM.

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Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
Raymund Dantes
1600 Clifton Rd
Atlanta, GA 30333
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800-232-4636

Long-Term Measure Steward
Centers for Disease Control and Prevention

Long-Term Measure Steward Contact Information
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800-232-4636

Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?
Yes/No: Yes
Justification and Notes: The Measure Under Consideration calculates the observed number of Healthcare-Associated Clostridioides difficile Infections (HA-CDI) at a health care facility, divided by the number of infections expected based on facility characteristics. This measure would update a very similar measure currently included in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQR), NQF#1717, by only counting cases where there was evidence of both a positive test and treatment. Measuring healthcare-associated infections is consistent with the Patient Safety Meaningful Measures 2.0 area.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?
Yes/No: Yes
Justification and Notes: After several years of implementation of HA-CDI quality measures, a 48% decrease in reported HA-CDIs was observed from 2015-2019. This indicates hospitals have successfully implemented initiatives, such as CDC guidelines for hand hygiene, that are reducing infection rates.

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This measure is intended to capture HA-CDI infections more precisely than the existing measure by only counting those infections among inpatients that both a position laboratory test and evidence of an antimicrobial agent administered to the patient two days before or after the positive test result.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: HA-CDI infections are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDI infections were reported to the CDC in 2019. CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures. According to NHSN reports, in 2019 nearly a third of reporting PPS-exempt cancer hospitals had an SIR higher than the national average, indicating a substantial range in performance.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: This measure would replace a similar, existing measure of HA-CDI infections observed/expected already included in the PCHQR. Versions of the same HA-CDI monitoring measure are also currently in use for quality reporting programs for acute care hospitals, long term care hospitals and inpatient rehabilitation facilities.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: All data elements required to calculate the measure are available in defined fields in electronic data. The HA-CDI measure currently implemented in the program has been successfully submitted by thousands of acute care hospitals for several years.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?

Yes/No: No

Justification and Notes: This measure is a specification update to an existing NQF-endorsed measure, #1717. The revised specifications have not been submitted to NQF for endorsement, and reliability and validity testing has not been finalized.

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?

Yes/No: No

Justification and Notes: The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test for CDI AND a treatment administered. This update is intended to mitigate instances where a facility or provider might be incentivized not to test for a suspected HA-CDI.

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- HAIs are extremely important to monitor

Data collection issues:

- None

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Calculation issues:

- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 4.0
1 – 0 votes
2 – 0 votes
3 – 1 votes
4 – 8 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.6
1 – 0 votes
2 – 1 votes
3 – 6 votes
4 – 9 votes
5 – 1 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This Measure Under Consideration would modify the existing HA-CDI surveillance measure in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQR), by only counting cases where there was evidence of both a positive test and treatment. This may mitigate potential unintended consequences from the current measure's design, counting a case based on a positive test only, which may have led to a historical under-counting of observed HA-CDI. This updated measure is consistent with the Patient Safety Meaningful Measures 2.0 area.

Summary: What is the potential impact of this measure on quality of care for patients?

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An HA-CDI infection has serious potential consequences for patients, including death. Nearly 114,000 HA-CDI were reported to the CDC in 2020. The performance of long-term care hospitals on the existing HA-CDI measure shows considerable variation in performance: in 2019, nearly a third of reporting PPS-exempt cancer hospitals had an SIR higher than the national average. Nevertheless, national performance across all reporting facilities has improved by 48% over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines.

MAP conditionally supports the measure for rulemaking, pending NQF endorsement and resolution of duplication concerns by CMS.

Section 3: Public Comments

Alliance of Dedicated Cancer Centers

The ADCC supports inclusion of this measure in the PCHQR program under certain conditions. We concur with the Hospital MAP that this measure should be included in the program pending NQF endorsement and with resolution of the duplication concerns by CMS. This measure is an improvement of the C. difficile measure currently included in the PCHQR program in that it is dependent upon the presence of both a positive culture and antibiotic therapy with vancomycin or fidaxomicin.

We have two important caveats to our recommendation: First, the PCHs that use PCR testing for C. difficile may be penalized unfairly because of the test's higher sensitivity than other testing options, and any differences in testing practices should be taken into consideration. Second, we recommend this measure be limited to inpatient only given the inherent challenges in capturing outpatient antibiotic therapy.

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MUC2021-091 Appropriate Treatment for Patients with Stage I (T1c) through III HER2 Positive Breast Cancer

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

Workgroup
Hospital

Measure Description
Percentage of female patients aged 18 to 70 with stage I (T1c) – III HER-2 positive breast cancer for whom appropriate treatment is initiated

Numerator
Patients whose adjuvant treatment course includes both chemotherapy and HER-2 targeted therapy

Numerator Exceptions
N/A

Denominator
Female patients with stage I (T1c) – III HER-2 positive breast cancer

Denominator Exclusions
Patients who are pregnant

Denominator Exceptions
- Patients with poor performance status (ECOG 3-4; Karnofsky = 50)
- Patients with cardiac contraindications
- Patients with insufficient renal function (eGFR < 10 ml/min; elevated creatinine or BUN; kidney failure)
- Patients with insufficient hepatic function (AST or ALT > 2-4 x ULN; bilirubin (total) > 2-4 x UL; hepatic failure)
- Patients with other active or secondary cancer diagnoses
- Patients with other medical contraindications
- Patients who died during initial treatment course or transferred during or after initial treatment course

State of development
Fully Developed

State of Development Details
Face validity testing was performed as part of alpha testing between November 01, 2019 and November 29, 2019 through a public comment survey. Feasibility testing was completed as part of alpha testing between November 04, 2019 and December 13, 2019. Finally, measure score reliability testing was carried out between March 08, 2021 and April 12, 2021 as part of beta testing.
Data collected showed that the measure was feasible (with all data elements in defined fields in electronic sources), and that the measure presented a below-average burden to the providers.

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Additionally, 88% of subject matter experts agreed that the medical terms, procedures, and diagnoses referenced in the measure specifications are appropriate and adequate, 94% of subject matter experts agreed that the performance score for the measure would be meaningful, understandable, and useful for public reporting, 88% of subject matter experts agreed that that the scores obtained from the measure will provide an accurate reflection of quality, and 94% of subject matter experts agreed that the measure results can be understood by the intended audience and are useful for decision making. Lastly, measure scores showed moderate reliability as indicated by an adjusted split-sample correlation coefficient of 0.6219.
For more details, please refer to the testing fields in this form.

What is the target population of the measure?
Medicare Fee for Service

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure
Medical oncology

Measure Type
Process

Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Electronic Health Record

If applicable, specify the data source
N/A

If EHR or Chart-Abstracted data, description of parts related to these sources
N/A

At what level of analysis was the measure tested?
Clinician; Group

In which setting was this measure tested?
Ambulatory/office-based care;Hospital outpatient department (HOD);PPS-exempt cancer hospital

What one healthcare domain applies to this measure?
Person-Centered Care

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
This measure could be linked to the below MIPS Cost measures, as the timely and appropriate numerator action of this measure can impact the overall cost attributed to clinicians by significantly improving patient overall survival:
MIPS Cost Measures:

1. Total Per Capita Cost
2. Medicare Spending Per Beneficiary

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This measure could be linked to the below listed MIPS Improvement Activities, as the measure addresses efficient and effective medical management of stage I (T1c)-III breast cancer patients through an appropriate treatment regimen.
MIPS Improvement Activities:

1. Implementation of medication management practice improvements ;This measure could be linked to the below MIPS Cost measures, as the timely and appropriate numerator action of this measure can impact the overall cost attributed to clinicians by significantly improving patient overall survival:

MIPS Cost Measures:

1. Total Per Capita Cost
2. Medicare Spending Per Beneficiary

This measure could be linked to the below listed MIPS Improvement Activities, as the measure addresses efficient and effective medical management of stage I (T1c)-III breast cancer patients through an appropriate treatment regimen.
MIPS Improvement Activities:

1. Implementation of medication management practice improvements

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
This submission is for the eCQM version of registry measure QID 450, also stewarded by the American Society of Clinical Oncology

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Digital Measure Information

Is this measure an electronic clinical quality measure (eCQM)?
Yes

If eCQM, enter Measure Authoring Tool (MAT) number
1002

If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
Yes

If eCQM, does any electronic health record (EHR) system tested need to be modified?
Yes

If yes, how would you describe the degree of effort?
3

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

Which measure(s) already in a program is your measure similar to and/or competing with?
This measure submission is for the eCQM version of the registry version of QID 450 (this is its eCQM counterpart).

How will this measure be distinguished from other similar and/or competing measures?
The existing registry CMQ 450 has been translated into an eCQM.

How will this measure add value to the CMS program?
This eCQM version will enable EHR submission of the registry version of QID 450.

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

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Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure

Approximately 15% of patients with breast cancer have tumors that overexpress the human epidermal growth hormone receptor protein (HER2). The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for the use of HER2-targeted therapy with chemotherapy for patients with stage I (T1c) – III, HER2 positive breast cancer. We recognize the importance of ensuring that the appropriate patient population receives guideline concordant treatment as studies have shown that the administration of HER2-targeted therapies significantly improves overall survival in patients with high-risk HER2 positive breast cancer.

Gradishar WJ, Anderson BO, Abraham J, et al. NCCN Guidelines Panel. NCCN Clinical Practice Guidelines in Oncology - Breast Cancer. Version 3. 2019. September 6, 2019.
https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

Wolff AC, Hammond MEH, Allison KH, Harvey BE, Mangu PB, Bartlett JMS, et al. Human Epidermal Growth Factor Receptor 2 Testing in Breast Cancer: American Society of Clinical Oncology/College of American Pathologists Clinical Practice Guideline Focused Update. J Clin Oncol. 2018 Jul 10; 36(20):2105-2122.

Evidence that the measure can be operationalized

Please refer to attached feasibility scorecard.

How is the measure expected to be reported to the program?

eCQM

Feasibility of Data Elements

ALL data elements are in defined fields in electronic health records (EHRs)

Evidence of Performance Gap

The previous version of QID 450 (the registry CQM counterpart) featured a numerator capturing the use of trastuzumab only, and historical MIPS data indicated this measure was topped out according to old specifications. The registry version of QID 450 has since been updated with an expanded numerator capturing appropriate therapy (i.e., use of both chemotherapy and HER2-targeted therapy) implemented in MIPS for the 2021 performance year. This submission is for the eCQM version of the updated specification for QID 450. ASCO anticipates the expanded numerator will result in a larger performance gap in both the CQM and eCQM submission methods.

Additionally, our testing results indicate that for an Electronic Clinical Quality Measure (eCQM) submission method, the mean performance rate is 0.4583 and the standard deviation is 0.2998. The mean and standard deviation were calculated based on the sample of 27 patients across 6 sites. Standard deviation was weighted to account for different number of patients per site. The results indicate there is still an existing performance gap and there is an opportunity for improvement.

Unintended Consequences

The TEP did not identify any unintended consequence with the measure if appropriately implemented and followed by eligible providers.

Outline the clinical guidelines supporting this measure

NCCN Recommendation for Adjuvant HER2-Targeted Therapy:

The panel has designated use of trastuzumab with chemotherapy as a category 1 recommendation in patients with HER2-positive tumors greater than 1 cm.

The American Society of Clinical Oncology (ASCO) envisions that use of this measure will improve concordance with recommendations for the use of HER2-targeted therapy with chemotherapy for

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patients with stage I (T1c) – III, HER2 positive breast cancer. We recognize the importance of ensuring that the appropriate patient population receives guideline concordant treatment as studies have shown that the administration of HER2-targeted therapies significantly improves overall survival in patients with high-risk HER2 positive breast cancer. This measure is supported by an evidence-based guideline recommendation.
Gradishar WJ, Anderson BO, Abraham J, et al. NCCN Guidelines Panel. NCCN Clinical Practice Guidelines in Oncology - Breast Cancer. Version 3. 2019. September 6, 2019.
https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf

Were the guidelines graded?
Yes

If yes, who graded the guidelines?
National Comprehensive Cancer Network (NCCN)

If yes, what was the grade?
Category 1; Based upon high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.

Estimated Impact of the Measure: Estimate of Annual Denominator Size
Unable to determine at this time. An estimate of the annual denominator size will be established once more data is collected.

Estimate of Annual Improvement in Measure Score
Not applicable at this time. An estimate of the annual improvement in measure score will be established once more data is collected.

Type of Evidence to Support the Measure
Clinical Guidelines

Is the measure risk adjusted, stratified, or both?
None

Are social determinants of health built into the risk adjustment model?
Not Applicable

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
Not applicable

Cost Avoided Annually by Medicare/Provider
Not applicable

Source of Estimate
Not applicable

Year of Cost Literature Cited
Not applicable

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

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If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys;Standard TEP; Other: Public Comment

Total Number of Clinicians/Providers Consulted
44

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
44

Burden for Provider: Was a provider workflow analysis conducted?
Yes

If yes, how many sites were evaluated in the provider workflow analysis?
4

Did the provider workflow have to be modified to accommodate the new measure?
Yes

If yes, how would you describe the degree of effort?
2

Does the measure require manual abstraction?
No

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If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
53

Measure Testing Details

Reliability Testing Interpretation of Results
The overall split-sample reliability score of 0.6219 is interpreted to indicate moderate reliability. This value demonstrates that the practice performance rate has moderate reliability, and that the measurement error is fairly reduced. Reliability coefficients between 0.5 and 0.75 reflect moderate precision between performance rates derived from the two samples (a reliability coefficient of greater than 0.90 represents excellent reliability).
Citation: Koo, T. K., & Li, M. Y. (2016). A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. Journal of chiropractic medicine, 15(2), 155–163. https://doi.org/10.1016/j.jcm.2016.02.012

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
Random Split Half Correlation

Reliability Testing Sample Size
Twenty-seven (27) patients across six (6) different sites satisfied the measure denominator and were chosen for performance score reliability testing. Each site had an average of five (5) patients. Of 27 patients, all 27, or 100%, were female. Additionally, 5 patients (19%) were African American, 2 patients (7%) were Asian, 3 patients (11%) were of unknown race, and 17 patients (63%) were White.

Reliability Testing Statistical Result
A split sample method of calculating reliability was used, where provider performance was measured once using a randomly chosen subset of the initial 27 patient sample and then measured again using the second random sample exclusive of the first. The agreement between the two resulting performance scores (one for each subset) was compared across 6 sites. As the metric of agreement, split-half coefficient was calculated. The unadjusted split-half coefficient was 0.4512. Spearman-Brown prophecy formula was used to adjust the split-half coefficient to provide an estimate that approximates as if entire sample was used for reliability calculation. The adjusted coefficient was 0.6219.

Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
N/A

Measure Score Validity
N/A

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Validity Testing: Type of Validity Testing Analysis

Face Validity; Internal Consistency

Validity Testing Sample Size

Face Validity: Sixteen (16) subject matter experts (SMEs) were surveyed for input on face validity of the measure during a public comment period that ran from November 01, 2019 to November 29, 2019. Internal Consistency: Six (6) sites encompassing twenty-seven (27) patients were chosen to assess the internal consistency of the measure.

Validity Testing Statistical Result

Face Validity:

Face validity of measure specifications, measure performance score, measure as assessment of quality of care, and interpretation of measure results was evaluated by surveying sixteen (16) subject matter experts (SMEs) via a web-based survey.

The survey asked subject matter experts' agreement with following statements:

- The medical terms, procedures and diagnoses referenced in the measure specifications are appropriate and adequate to accomplish the measurement goal and align with the evidence base as currently known.
- The performance score for the measure would be meaningful, understandable, and useful for public reporting.
- The scores obtained from the measure, as specified, will provide an accurate reflection of quality, and can be used to distinguish good and poor quality.
- The measure results can be understood by the intended audience (e.g., consumers, purchasers, providers, policy makers), and they are likely to find them useful for decision making.
- Respondents indicated the extent to which they agreed with each statement on a 5-point Likert scale (5 = Strongly agree; 4 = Agree; 3 = Neutral; 2 = Disagree; 1 = Strongly disagree).
- Feedback received from survey respondents showed that:
- 25% strongly agreed and 63% agreed that the medical terms, procedures, and diagnoses referenced in the measure specifications are appropriate and adequate
- 44% strongly agreed and 50% agreed that the performance score for the measure would be meaningful, understandable, and useful for public reporting
- 19% strongly agreed and 69% agreed that the scores obtained from the measure will provide an accurate reflection of quality, and
- 38% strongly agreed and 56% agreed that the measure results can be understood by the intended audience and are useful for decision making.

Internal Consistency:

A split sample method of calculating internal consistency was used, where provider performance was measured once using a randomly chosen subset of the initial 27 patient sample and then measured again using the second random sample exclusive of the first. The agreement between the two resulting performance scores (one for each subset) was compared across 6 sites. As the metric of agreement, split-half coefficient was calculated. The unadjusted split-half coefficient was 0.4512. The adjusted split-half coefficient, an estimate that approximates as if entire sample was used for internal consistency calculation, was 0.6219.

Validity Testing Interpretation of Results

Face Validity:

The agreement on the face validity of the measure was high:

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- 88% of subject matter experts agreed that the medical terms, procedures, and diagnoses referenced in the measure specifications are appropriate and adequate
- 94% of subject matter experts agreed that the performance score for the measure would be meaningful, understandable, and useful for public reporting
- 88% of subject matter experts agreed that that the scores obtained from the measure will provide an accurate reflection of quality, and
- 94% of subject matter experts agreed that the measure results can be understood by the intended audience and are useful for decision making.

Internal Consistency:
The overall split-sample coefficient of 0.6219 is interpreted to indicate moderate internal consistency. This value shows that a provider performs fairly consistently on the measure regardless of which subset of their patients is chosen to calculate their measure performance.

Measure performance – Type of Score
Proportion

Measure Performance Score Interpretation
Higher score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
For an Electronic Clinical Quality Measure (eCQM) submission method, the mean performance rate is 0.4583 and the standard deviation is 0.2998. The mean and standard deviation were calculated based on the sample of 27 patients across 6 sites. Standard deviation was weighted to account for different number of patients per site. The results indicate there is still an existing performance gap and there is an opportunity for improvement.

Benchmark, if applicable
Not applicable at this time. The benchmark will be established once more data is collected on the measure.

Measure Contact Information

Measure Steward
American Society of Clinical Oncology

Measure Steward Contact Information
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Long-Term Measure Steward
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N/A

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Secondary Submitter Contact Information
N/A

Section 2: Preliminary Analysis – MUC2021-091 Appropriate Treatment for Patients with Stage I (T1c) through III HER2 Positive Breast Cancer

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: This Measure does not align with the 2021 Needs and Priorities for this program: Patient-reported Outcome-Based Performance Measures (PRO-PMs), Care Coordination, or Behavioral Health. However, this measure does align with the CMS Meaningful Measures Framework in that it is an eCQM and may support greater access to life-saving diagnostics and therapies during the COVID-19 public health emergency (PHE) and beyond.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: This measure aims to identify the percentage of female patients aged 18 to 70 with stage I (T1c) – III HER-2 positive breast cancer for whom appropriate treatment is initiated. Approximately 15% of breast cancer patients present overexpression of the human epidermal growth hormone receptor protein (HER2) within their tumor. Studies have shown that overall survival of patients with high-risk HER2 positive breast cancer significantly increased with the administration of HER2-targeted therapies (Sikov, 2021). The American Society of Clinical Oncology (ASCO) proposes that this measure will better align patients with stage I (T1c) - III, HER2 positive breast cancer with HER2-targeted therapy with chemotherapy, for improved health outcomes (more effective inhibition of HER2, pathologic complete response (pCR) rate, recurrence rate, event-free survival (EFS), and overall survival (OS)), based on evidence within the National Comprehensive Cancer Network (NCCN) 2020 Guidelines and other clinical trial data (Gradishar et al., 2020; Sikov, 2021).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer reports a mean performance rate of 0.4583 and a standard deviation of 0.2998 for this Electronic Clinical Quality Measure (eCQM) submission method. Standard deviation was weighted to account for different number of patients per site. The results indicate there is still a quality challenge based on an existing performance gap across the sample of 27 patients within six sites.

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Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?
Yes/No: Yes

Justification and Notes: The measure is not duplicative of an existing measure or measure under consideration in this program. This measure is an eCQM, which contributes to efficient use of measurement resources. Additionally, this measure could be used across other programs to promote alignment.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: The developer states that all data elements required for this measure are available in defined fields in an electronic source. Evidence to support this claim was provided by the eCQM feasibility scorecards for several sites.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: No

Justification and Notes: This measure will be collected at the level of clinician/clinician group and was tested for reliability and validity at the measure score-level. The random split-half correlation reliability score obtained from 27 patients across six sites was 0.6219. Measure score validity was tested through both face validity and internal consistency. Face validity was obtained from sixteen subject matter experts (SMEs) who provided strong agreement (ranges 88-94%) on the medical terms and procedures used within the measure, the importance of public reporting, the reflection of quality, and the usefulness for decision making. Internal consistency testing resulted in an overall split-sample coefficient of 0.6219. In addition, validity testing of the critical data elements (e.g., numerator, denominator) should be considered. Lastly, this measure is not NQF-endorsed.

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?
Yes/No: N/A

Justification and Notes: The measure is not currently in use and the measure developers did not identify any unintended consequences.

PAC/LTC Core Concept?
Yes/No: N/A

Justification: N/A

Impact Act Domain
Yes/No: N/A

Justification: N/A

Hospice High Priority Areas
Yes/No: N/A

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Justification: N/A

MAP Rural Health Advisory Group Input:

Relative priority/utility:

- This may not be applicable for rural providers as the program is for 11 participating cancer hospitals
- However, from a rural perspective this measure has some importance for rural providers, such that they know whether treatment has been initiated for their patients

Data collection issues:

- There was discussion on how providers would collect and report on the measure. There was discussion that the oncologist will need to execute an order to fulfill the measure, which these specialists are sparse in some rural areas

Calculation issues:

- None

Unintended consequences:

- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.4
1 – 1 votes
2 – 2 votes
3 – 6 votes
4 – 5 votes
5 – 3 votes

MAP Health Equity Advisory Group Input:

Relative priority/utility:

- Concern that this measure is not stratified by race and ethnicity, and other social determinants of health and collecting these data will be very important

Data collection issues:

- None

Calculation issues:

- None

Unintended consequences:

- Concern that any time that a measure has voluntary reporting (such as with the PCHQR program) lends itself vulnerable to cherry-picking

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 2.5
1 – 4 votes

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2 – 5 votes
3 – 3 votes
4 – 5 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This measure does not align with the 2021 Needs and Priorities for this program: Patient-reported Outcome-Based Performance Measures (PRO-PMs), Care Coordination, or Behavioral Health. However, this measure does align with the CMS Meaningful Measures Framework in that it is an eCQM and may support greater access to life-saving diagnostics and therapies during the COVID-19 public health emergency (PHE) and beyond.

Summary: What is the potential impact of this measure on quality of care for patients?
This measure aims to identify the percentage of female patients aged 18 to 70 with stage I (T1c) – III HER-2 positive breast cancer for whom appropriate treatment is initiated. Studies have shown that overall survival of patients with high-risk HER2 positive breast cancer significantly increased with the administration of HER2-targeted therapies (Sikov, 2021). Although this measure has undergone measure score reliability and validity testing, validity testing of the critical data elements (e.g., numerator, denominator) should be considered. The measure does not currently have NQF endorsement. MAP recommended conditional support for rulemaking pending NQF endorsement.

Section 3: Public Comments

American Society of Clinical Oncology
ASCO supports the inclusion of MUC2021-091 to the PCHQR program. ASCO anticipates this measure will add value, as approximately 15% of patients with breast cancer have tumors that overexpress the human epidermal growth hormone receptor protein (HER2), and it is imperative that they receive appropriate clinical care reflective of their HER2 status. We envision that use of this measure will improve concordance with recommendations for the use of HER2-targeted therapy with chemotherapy for patients with stage I (T1c) – III, HER2 positive breast cancer. Additionally, this measure will improve patient outcomes by encouraging the appropriate receipt of guideline-concordant treatment, as studies have shown that the administration of HER2-targeted therapies significantly improves overall survival in patients with high-risk HER2 positive breast cancer.

A provider analysis conducted by the measure developer indicated that to report the measure, workflow modifications required only low effort (2 on a scale from 1-5, where 1 is little to no effort and 5 is substantial effort) and the measure does not require manual abstraction. Data collection during feasibility testing indicated the measure presented a below-average burden to the providers. ASCO believes the benefits of this measure in significantly improving overall survival in patients with high-risk

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HER2 positive breast cancer through appropriate treatment greatly outweighs any potential data collection or reporting burden.

College of American Pathologists

The College of American Pathologists supports this measure as an important consideration for managing patients as part of an individual care plan that includes genetic testing as clinically indicated, appropriate follow up, and personalized treatment.

The Coalition to Transform Advanced Care

We support this measure and see its value as confirming that any treatment delivered be in line with what the team and patient agree is appropriate. That has the potential to improve cancer treatment outcomes for this patient population. However, we recommend that a similar measure be also developed/considered for patients with other cancers or serious illness to ensure the care provided to them is also appropriate.

This measure could be used for QI, certification, accreditation, payment, and public reporting purposes.

Our implementation question is clarifying what is meant by “appropriate” treatment for this measure and we recommend that it also include input from the patient. While we support treatments in line with evidence-based clinical practice guidelines, we also know that people with breast cancer have their own personal goals and priorities and so need a customized treatment plan that is appropriate for them, and which balances the potential benefits and burdens of such treatment on them and their families including financial implications.

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 Measures Application 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 assessment of surgical care value 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.

ACS seeks clarification on the Appropriate Treatment for Patients with Stage I (T1c) through III HER2 Positive Breast Cancer measure. It is unclear how the numerator for the measure is determined. Appropriateness is conceptually attractive but extremely complex and difficult to implement. Appropriateness requires a standard as well as a means of establishing the standard is met. It also varies with the patient’s goals, age, and other factors, making this a very heterogenous, complex standard. Other aspects of appropriateness include drug selection, consideration of enrollment in clinical trials, updated treatment guidelines and so forth. Is there a list of drugs that are deemed appropriate? We also believe it is important that “appropriate” is clearly defined. For example, does this measure include any use of the right drug? What if the drug is administered at half the dose, is that considered appropriate? What happens when treatment involves cycles of therapy and the cycles are outside the standard or they are not fully completed? What if a different drug not on a list of appropriate treatments is used?

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Additionally, in the exclusions, “patients with other contraindications’ seems very broad. What if they choose not to have treatment? We also seek clarity on whether there is an exception for patients in a clinical trail.

Additionally, advances in digital tracking of appropriate care are in early stages of development. These would allow for case management, business process management of care and for decision management of care. The digital services create human readable care pathways that are also computably executable. Simply put, this allows for digital systems to track conformance (appropriateness) with standards of care, with warranted variation from standards and with notations for unwarranted care. Until these services are tested for reliability and validity, appropriateness of care measures are difficult due to all the complexity suggested in our comments above.

American Hospital Association

The AHA agrees with the MAP’s recommendation of Conditional Support. Conceptually, the measure addresses an important quality issue. We have some questions about the mechanics of the measure that we believe will be borne out through the endorsement process, specifically validity testing of the critical data elements at the facility level.

Alliance of Dedicated Cancer Centers

We do not support this measure for inclusion in the PCHQR Program. From the materials made available to us, it appears that this measure is an eCQM version of the NQF-endorsed measure #1858, “#Trastuzumab administered to patients with AJCC stage I (T1c) – III human epidermal growth factor receptor 2 (HER2) positive breast cancer who receive adjuvant chemotherapy”. This is an evidenced-based measure. However, the primary reason for our opposition to including this measure in the PCHQR program is that performance is most likely already topped out. In the most recent data (2019) submitted to NQF data at both the TIN and NPI level showed that the majority were already “topped out” according to the measure steward. This was particularly true for the higher volume providers, a group which the PPS-exempt Cancer Hospitals (PCHs) would most certainly be a part of. Without analysis showing a performance gap within the PCHs we do not believe this measure would add value.

Furthermore, there would be a significant data collection and reporting burden to the PCHs. Traditionally performance for the measure NQF #1858 has been gathered through manual chart abstraction and in the cancer registries. While we appreciate the development of an eCQM in support of CMS Meaningful Measures Framework, at this time many of the data elements including staging, date of diagnosis (which often occurs outside of the PCH), and the numerous exclusion criteria are not discretely documented in the electronic health records. To prepare for this measure as an eCQM would require a significant investment and burden from the PCHs. This cost is most likely not supported given the fact that performance is most likely topped out. It is unclear from the materials supplied for review if the performance gap the measure steward cited was due to a lack of documentation in the fields used for this eCQM, or true issues with clinical practice. We suspect the former.

Lastly, this is a process measure, which is not in alignment with the emphasis currently placed on outcomes.

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MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Section 1: Measure Information

Measure Specifications and Endorsement Status

Program
PPS-Exempt Cancer Hospital Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Medicare Promoting Interoperability Program for Hospitals, Hospital IQR Program

Workgroup
Hospital

Measure Description
This measure tracks the development of new bacteremia and fungemia among patients already admitted to acute care hospitals, using algorithmic determinations from data sources widely available in electronic health records. This measure includes many healthcare-associated infections not currently under surveillance by the Center for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN). Ongoing surveillance also requires minimal data collection burden for users.

Numerator
Observed number of Hospital-Onset Bacteremia & Fungemia (HOB) events, defined below:
Must meet Bacteremia OR Fungemia criteria (BFC), AND Antimicrobial treatment criteria (ATC).
Bacteremia OR Fungemia criteria (BFC):
Patient of any age has a recognized bacterial or fungal pathogen from a blood specimen collected on the 3rd calendar day of admission or later (where the date of admission to an inpatient location is calendar day 1). The pathogen must not be included on the NHSN common commensal list, and meet EITHER of the following criteria:

1. Pathogen identified by culture of one or more blood specimens, OR
2. Pathogen identified to the genus or species level by non-culture based microbiologic testing (NCT) methods. Note: if blood is collected for culture within 2 days before, or 1 day after the NCT disregard the result of the NCT and use only the result of the CULTURE to make a BFC determination. If no blood is collected for culture within this time period, use the result of the NCT for BFC determination.

Antimicrobial Treatment Criteria (ATC):
A patent must have been administered at least 1 dose of an intravenous or oral (including all enteral routes) antimicrobial in the window period extending 2 calendar days before and 2 calendar days after the date of blood specimen collection for BFC. The date of blood specimen collection is day 0. Furthermore, if the patient had Bacteremia, only antibiotics are eligible to meet the ATC criteria. Similarly, if the patient has Fungemia, only antifungals are eligible to meet ATC criteria. If a patient has both Bacteremia and Fungemia, then either an antibiotic or antifungal can meet the ATC criteria.

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Numerator Exceptions

1) Previous matching Present on Admission Bacteremia or Fungemia
If a patient meets BFC but also had a pathogen matching to the same species or genus level identified from a blood specimen by culture or NCT that was collected in the Present on Admission (POA) window, defined as hospital calendar day 2 or earlier (where calendar date of admission to an inpatient location is day 1), then this BFC is excluded from the HOB measure.
If multiple pathogens are identified from the same blood culture or NCT, then a match of any of those pathogens to a POA blood pathogen is sufficient to exclude the BFC from the HOB measure.
2) Previous HOB event
A patient with a previous HOB event is excluded from additional HOB events during the same hospital admission.

Denominator

The expected number of HOB events based on predictive models using facility- and patient care location data as predictors.

Denominator Exclusions

Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts. Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

Denominator Exceptions

Under investigation, subject to change.

State of development

Specification

State of Development Details

Specification: The measure stewards have partnered with several research groups to evaluate HOB in different populations of hospitalized patients. All studies are considered alpha testing, and are ongoing:
A) Hospital-Onset Bacteremia & Fungemia Preventability Evaluation (HOPE): Two components

1. Evaluation of sources and preventability of HOB events in ~2400 adult and pediatric patients across 13 hospitals. Results expected summer/fall 2021.
2. HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes, and risk factors for HOB in Cerner Healthfacts and Premier Healthcare Databases (500 hospitals, 18,000,000 admissions). Results expected summer 2021.

B) Becton Dickinson: HOB definition sensitivity analysis, evaluation of epidemiology, patient outcomes and cost, risk factors, and surveillance feasibility for HOB in 271 hospitals, 8,000,000 admissions. Results expected summer/fall 2021.
C) Veterans Affairs: HOB definition sensitivity analysis, chart review validation, evaluation of epidemiology, surveillance feasibility in 142 hospitals, 1,700,000 admissions. Results expected summer 2021.

What is the target population of the measure?

All Payer

Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure

Infectious disease

Measure Type

Outcome

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Is the measure a composite or component of a composite?
No

If Other, Please Specify
N/A

What data sources are used for the measure?
Administrative Data (non-claims); Electronic Health Record

If applicable, specify the data source
CDC, NHSN (National Healthcare Safety Network)

If EHR or Chart-Abstracted data, description of parts related to these sources
1) Microbiology records of blood cultures and NCT, typically from an EHR laboratory information system.
2) Medication administration records (eg. antimicrobial administration), from EHR.
3) Administration records, non-claims (eg. date of admission, discharge, patient location).
The HOB measure requires linking relevant microbiological test results for blood cultures and NCT with applicable antimicrobial administration records from the medication administration records, and algorithmically determining the measure using the time windows dictated by the administration records.

At what level of analysis was the measure tested?
Facility

In which setting was this measure tested?
Community hospital; Hospital inpatient acute care facility; Veterans Health Administration facility

What one healthcare domain applies to this measure?
Safety

MIPS Quality: Identify any links with related Cost measures and Improvement Activities
N/A

CMIT ID
N/A

Alternate Measure ID
N/A

What is the endorsement status of the measure?
Never Submitted

NQF ID Number
N/A

If endorsed: Is the measure being submitted exactly as endorsed by NQF?
N/A

If not exactly as endorsed, specify the locations of the differences
N/A

If not exactly as endorsed, describe the nature of the differences
N/A

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If endorsed: Year of most recent CDP endorsement
N/A

Year of next anticipated NQF Consensus Development Process (CDP) endorsement review
N/A

Submitter Comments
N/A

Digital Measure Information

Is this measure an electronic clinical quality measure (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 in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?
N/A

If eCQM, does any electronic health record (EHR) system tested need to be modified?
N/A

If yes, how would you describe the degree of effort?
N/A

Measure Use in CMS Programs

Was this measure proposed on a previous year's Measures Under Consideration list?
No

Previous Measure Information
N/A

What is the history or background for including this measure on the new measures under consideration list?
New measure never reviewed by Measure Applications Partnership (MAP) Workgroup or used in a CMS program

Range of years this measure has been used by CMS Programs
N/A

What other federal programs are currently using this measure?
N/A

Is this measure similar to and/or competing with a measure(s) already in a program?
Yes

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Which measure(s) already in a program is your measure similar to and/or competing with?
MUC2019-19: "National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection Outcome Measure"
MUCFIFTEEN-532MRSA: "National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia Outcome Measure"

How will this measure be distinguished from other similar and/or competing measures?
The HOB outcome measure collects the number of bloodstream infections that occur during hospitalization (and not present on admission) due to a broad range of pathogenic bacteria and fungi (in contrast to the narrower MRSA measure), and regardless of whether the infection was attributable to a central line or device (in contrast to the narrower CLABSI measure).
Furthermore, the inclusion of evidence of antimicrobial treatment for the HOB measure increases the clinical validity of the measure by acting as a proxy for true infections requiring treatment from the provider. This component may become more valuable as emerging non-culture based microbiologic testing (NCT) become more ubiquitous. These tests may have increased false positive signals or could detect pathogen genetic material that may not correspond to live pathogens causing an ongoing bacteremia or fungemia. Thus, requiring evidence of antimicrobial treatment serves as a proxy for the clinical interpretation of infection by the provider.

How will this measure add value to the CMS program?
The HOB outcome measure includes most to nearly all central-line associated bloodstream infections and MRSA bacteremias, and many more bloodstream infections that cause healthcare associated infections but are not currently under surveillance for quality measurement. Preliminary data suggests a substantial percentage of HOB events are preventable under current infection prevention standards, and we anticipate that use of an HOB outcome measure will encourage innovation to identify new methods for reducing these infections.
Furthermore, the HOB measure uses an algorithmic approach to determine events, thus reducing regular data collection burden and subjectivity from event determination. "HOB surveillance could inform broad measures to improve infection control in conjunction with other HAI data, potentially resulting in measurably improved patient outcomes. HOB data collection and reporting burden would likely be low given the ubiquity and functionality of current EHRs, in contrast to NHSN CLABSI and other measures that call for substantial investments of time and effort in manual reviews of healthcare records."(1)
References:
1) Dantes et al. Hospital epidemiologists' and infection preventionists' opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540

If this measure is being proposed to meet a statutory requirement, please list the corresponding statute
N/A

Measure Evidence

Briefly describe the peer-reviewed evidence justifying this measure
Multiple justification studies are underway.

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An HOB measure is viewed favorably among subject matter experts and users. A survey of 89 researchers in the Society for Hospital Epidemiology of America (SHEA) Research Network found that "Among the majority of SHEA Research Network respondents, HOB is perceived as preventable, reflective of quality of care, and potentially acceptable as a publicly reported quality metric." Furthermore, "Given a choice to publicly report central-line-associated bloodstream infections (CLABSIs) and/or HOB, 57% favored reporting either HOB alone (22%) or in addition to CLABSI (35%) and 34% favored CLABSI alone. (1)

References

1) Dantes et al. Hospital epidemiologists' and infection preventionists' opinions regarding hospital-onset bacteremia and fungemia as a potential healthcare-associated infection metric. Infection Control and Hospital Epidemiology, 01 Apr 2019, 40(5);536-540.

Evidence that the measure can be operationalized

The HOB measure leverages sources of data, primarily microbiology and medication administration data, that are already used for many existing CDC National Healthcare Safety Network (NHSN) measures and reported to CMS on a quarterly basis.

How is the measure expected to be reported to the program?

Other: CDC NHSN submission to CMS

Feasibility of Data Elements

ALL data elements are in defined fields in a combination of electronic sources

Evidence of Performance Gap

Interim and preliminary analysis from the HOPE study with approximately half the data collected shows approximately 41% of HOB events were considered preventable after expert review. Final results expected summer/fall 2021.

Unintended Consequences

It is possible that providers and facilities may be discouraged from ordering blood cultures or NCT among patients that are later into their hospitalization when they suspect an infection.

Outline the clinical guidelines supporting this measure

N/A

Were the guidelines graded?

N/A

If yes, who graded the guidelines?

N/A

If yes, what was the grade?

N/A

Estimated Impact of the Measure: Estimate of Annual Denominator Size

Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

Estimate of Annual Improvement in Measure Score

To be determined.

Type of Evidence to Support the Measure

Empirical data

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Is the measure risk adjusted, stratified, or both?
Risk adjusted

Are social determinants of health built into the risk adjustment model?
Yes

Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event
For hospitalizations with an HOB event, the mean unadjusted cost is ~$83,000 (median $44,000). As an unadjusted, unmatched comparison group, hospitalizations with negative blood cultures had an average cost of ~$45,000 (median $26,000). (Data via Becton Dickinson analysis)

Cost Avoided Annually by Medicare/Provider
Unable to determine at this time.

Source of Estimate
Data from Becton Dickinson analysis of 85 hospitals from October 2015 through June 2019.

Year of Cost Literature Cited
October 2015 through June 2019

Patient and Provider Perspective

Meaningful to Patients: Was input collected from patient and/or caregiver?
No

If yes, choose all methods of obtaining patient/caregiver information
N/A

How many times and at what phase(s) of measure development was the patient/caregiver engaged?
N/A

Total Number of Patients and/or Caregivers Consulted
N/A

Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups
N/A

Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions
N/A

Burden for Patient: Does the measure require survey data from the patient?
No

If yes, what is the estimated time to complete the survey?
N/A

If yes, what is the frequency of requests for survey data per year?
N/A

If yes, are the survey data to be collected during or outside of a visit?
N/A

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Meaningful to Clinicians: Were clinicians and/or providers consulted?
Yes

If yes, choose all methods that obtained clinician and/or provider input
Surveys

Total Number of Clinicians/Providers Consulted
76

Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care
41

Burden for Provider: Was a provider workflow analysis conducted?
No

If yes, how many sites were evaluated in the provider workflow analysis?
N/A

Did the provider workflow have to be modified to accommodate the new measure?
No

If yes, how would you describe the degree of effort?
N/A

Does the measure require manual abstraction?
No

If yes, what is the estimated time per record to abstract data?
N/A

How many data elements will be collected for the measure?
No manually abstracted data elements are required for this measure.

Measure Testing Details

Reliability Testing Interpretation of Results
IRR to be performed in Veterans Affairs project summer 2021

Type of Reliability Testing
Measure Score Reliability

Reliability Testing: Type of Testing Analysis
IRR (Inter-rater reliability)

Reliability Testing Sample Size
IRR to be performed in Veterans Affairs project summer 2021

Reliability Testing Statistical Result
IRR to be performed in Veterans Affairs project summer 2021

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Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?
No

If yes, specify the number of cases and the percentage of providers
N/A

Type of Validity Testing
Measure Score Validity; Data Element Validity

Validity Testing: Type of Validity Testing Analysis
Construct Validity

Validity Testing Sample Size
Planned for Veterans Affairs project summer 2021.

Validity Testing Statistical Result
Planned for Veterans Affairs project summer 2021.

Validity Testing Interpretation of Results
Planned for Veterans Affairs project summer 2021.

Measure performance – Type of Score
Ratio

Measure Performance Score Interpretation
Lower score is better

Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have
HOB performance will be measured using methods already in use for other CDC NHSN measures: the Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).
Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HOB events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

1. Identify the number of unique HOB events for a given time period by adding the total number of observed events across the facility.
2. Calculate the number of expected HOB events for the facility using the negative binomial regression model
3. Divide the number of observed HOB events (1 above) by the number of expected HOB events (2 above) to obtain the SIR.
4. Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

The Adjusted Ranking Metric (ARM) for annual data aggregation and analysis of HAI events, including HOB events, combines the method of indirect standardization used to calculate the unadjusted SIR described above with a Bayesian random effects hierarchical model to account for the potentially low precision and/or reliability inherent in the unadjusted SIR. A Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling is used to produce the adjusted numerator. The ARM enables more meaningful statistical differentiation between hospitals by accounting for differences in patient case-mix, exposure volume (e.g. patient days), and unmeasured factors that are not reflected in

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the unadjusted SIR and that cause variation between healthcare facilities. Accounting for these sources of variability enables better measure discrimination between facilities and leads to more reliable performance rankings. To produce the ARM:

1. Identify the number of HOB events for the facility
2. Obtain the adjusted number of observed HOB for the facility using a Bayesian posterior distribution constructed through Monte Carlo Markov Chain sampling which results from a Bayesian random effects model.
3. Total these numbers for an observed HOB events
4. Obtain the expected number of HOB events
5. Divide the total number of adjusted HOB events (3 above) by the predicted number of HOB events (4 above) to obtain the ARM.
6. Perform a Poisson test to compare the SIR obtained in 5 above to the nominal value of 1. P-value and confidence interval will be calculated, which can be used to assess significance of SIR.

Benchmark, if applicable
See description of SIR and ARM above.

Measure Contact Information

Measure Steward
Centers for Disease Control and Prevention

Measure Steward Contact Information
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Long-Term Measure Steward
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Primary Submitter Contact Information
N/A

Secondary Submitter Contact Information
N/A

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Section 2: Preliminary Analysis – MUC2021-100 National Healthcare Safety Network (NHSN) Hospital-Onset Bacteremia & Fungemia Outcome Measure

Does the measure address a critical quality objective not currently adequately addressed by the measures in the program set?

Yes/No: Yes

Justification and Notes: This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. Although this measure does not address the Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQR)'s measurement priorities, the measure is consistent with the Patient Safety Meaningful Measure 2.0 area. There are two measures currently included in PCHQR, whose measure result would, in part, be reflected in this proposed measure: (1) the NHSN MRSA bacteremia measure, and (2) the NHSN CLABSI measure. However, the proposed measure vastly increases the number of applicable microorganisms and attributable causes that would be captured in the measure.

Is the measure evidence-based and either strongly linked to outcomes or an outcome measure?

Yes/No: Yes

Justification and Notes: There is evidence that the HOB tracked by this outcome measure can be prevented by hospitals; one 2017 study by Dantes et al estimated that 49% of HOB infections were potentially preventable, and a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists estimated that 50% or more of HOBs could be prevented, with a variety of hospital practices identified that could reduce HOBs. In an unpublished analysis of healthcare data by the measure submitter, hospitalizations with an HOB were found to be nearly twice as expensive as those without (average cost of $83,000 compared to $45,000).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: HOB are common infections, especially relative to other infections currently measured in quality reporting programs: for example, a 2015 study by Rock et al found that HOB infections were 17 times as likely to be observed in an ICU compared to CLABSI infections. The same study concluded that a change in HOB rate has a greater power to discriminate between ICU performance than CLABSI rates. Contracting an HOB leads to a greatly increased risk of mortality, as found by Lambert et al, 2011. The developer also cites preliminary results from the HOPE study analysis in which approximately 41% of HOB events were considered preventable after expert review. The developer notes that final study results are expected summer/fall 2021. Although performance data for this measure are not yet available, a 2019 survey by Dantes et al of hospital epidemiologists and infection preventionists found that 54% agreed that the measure concept would reflect quality of care at a hospital.

Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?

Yes/No: Yes

Justification and Notes: There are two measures currently included in PCHQR, whose measure result

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would, in part, be reflected in this proposed measure: (1) the NHSN MRSA bacteremia measure, and (2) the NHSN CLABSI measure. However, the proposed measure vastly increases the number of applicable microorganisms and attributable causes that would be captured in the measure. For example, one 2015 study by Rock et al found that HOB infections were 17 times as likely to be observed in an ICU compared to CLABSI infection, leading to additional discriminatory power for the measure result. Likewise, a 2017 study by Dantes et al estimated that just 10% of all bacteremia and fungemia observed across three academic medical centers were *s. aureus*. Therefore, adding this measure to the PCHQR program would represent adding surveillance events that are mostly not captured by existing measures.

Can the measure be feasibly reported?
Yes/No: Yes

Justification and Notes: All data elements are available in defined electronic fields; no data abstraction is required.

Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?
Yes/No: No

Justification and Notes: The measure is specified for the appropriate care setting, level of analysis, and patient population. However, no reliability or validity testing of the measure result has been conducted, and the measure has not been reviewed for endorsement by the National Quality Forum.

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?
Yes/No: Yes

Justification and Notes: Although the measure has not been implemented or tested in a healthcare facility, one possible unintended consequence that the developer identified is that the measure may discourage providers and hospitals from testing patients where they suspect a bacteremia or fungemia infection.

PAC/LTC Core Concept?
Yes/No: N/A

Justification: N/A

Impact Act Domain
Yes/No: N/A

Justification: N/A

Hospice High Priority Areas
Yes/No: N/A

Justification: N/A

MAP Rural Health Advisory Group Input:
Relative priority/utility:

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- HAIs are extremely important to monitor

Data collection issues:
- None

Calculation issues:
- Low case volume is a potential challenge for measure calculation and reporting. The Advisory Group encouraged the developer to account for small volume providers
- For critical access hospitals, they do not participate in the IQR, but this measure does apply to the PPS hospitals

Unintended consequences:
- None

Votes: Range is 1 – 5, where higher is more relevant to rural.
Average: 3.8
1 – 0 votes
2 – 1 votes
3 – 1 votes
4 – 8 votes
5 – 1 votes

MAP Health Equity Advisory Group Input:
The Advisory Group did not have time to discuss this measure and voting occurred offline. Results are below, and no additional comments from the Health Equity Advisory Group were received.

Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity
Average: 3.5
1 – 0 votes
2 – 1 votes
3 – 6 votes
4 – 10 votes
5 – 0 votes

Recommendation

Preliminary Analysis Recommendation:
Conditional Support for Rulemaking

Summary: What is the potential value to the program measure set?
This measure tracks the number of hospital-onset bacteremia or fungemia infections (HOB), indicated by positive test results, among inpatients – but excluding those present on admission or for which not treatment was administered. Although this measure does not address the Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQR)'s measurement priorities, the measure is

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consistent with the Patient Safety Meaningful Measure 2.0 area. There is some overlap with the existing CLABSI and MRSA measures in the program set; nevertheless, adding this measure to the PCHQRP program would add surveillance of infections that are mostly not captured by either of those measures.

Summary: What is the potential impact of this measure on quality of care for patients?
This Measure Under Consideration tracks a group of very common, and potentially lethal, hospital-acquired infections. Hospitalizations where these conditions were identified were nearly twice as expensive as the average hospital stay, indicating high resource utilization needed to treat these conditions. Despite the common and costly nature of these infections, studies and surveys estimate that nearly half of these infections are preventable by the hospital. Incentivizing the adoption of infection control practices that would reduce the incidence of these conditions would present a substantial benefit to both patients and the health care system.

MAP conditionally supported the measure for rulemaking, pending NQF endorsement.

Section 3: Public Comments

Johnson & Johnson
Johnson & Johnson agrees with the MAP's recommendation of conditional support for this measure. This measure encourages hospitals to take precautions that prevent hospital-onset bacteremia and fungemia. By holding hospitals accountable for the development of new bacteremia and fungemia infections, this measure promotes patient safety, improves quality outcomes and seeks to contain avoidable infections and excess costs. In general, Johnson & Johnson supports measures that incentivize management and reduction of hospital-onset infections and addresses Hospital-Acquired Condition Reduction Program measurement priorities.

Alliance of Dedicated Cancer Centers
The ADCC does not support this inclusion of this measure in the PCHQR program. We agree that a measure to assess bacterial and fungal infections could drive improved patient care, but this measure is not mature enough to include in the PCHQR program. The rationale for the measure states that multiple justification studies are underway. It would be preferrable to see the results of these studies prior to inclusion of this measure in the program. In addition, many immunocompromised patients develop infections that are not always preventable or reflective of the quality of care they receive but are due to the patient's clinical condition. This metric does not exclude patients with severe neutropenia or GI graft versus host disease who may develop infections because of a non-intact mucosa rather than because of the care they receive (these are the patients that currently meet the MBI – mucosal barrier injury – NHSN definition). Furthermore, many of cancer patients who are immunocompromised or who received BMT or cellular therapy are on antimicrobial therapy for prophylactic reasons. Lastly, implementing this measure would require significant effort on behalf of nursing and infection control staff who are heavily burdened by COVID-related issues. In sum, the implementation burden, particularly given the strain on staff resources as a result of COVID, outweigh the benefits of this measure.

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