

Measure Applications Partnership (MAP) Hospital Workgroup

Preliminary Analyses

December 01, 2022

Last updated: January 17, 2023

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Preliminary Analysis – MUC2022-028 ASC Facility Volume Data on Selected Surgical Procedures (formerly ASC-7)

Measure Description:

Structural measure of facility capacity collects surgical procedure volume data on selected categories of procedures frequently performed in the ASC setting Categories include: Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous, Respiratory, Skin, and Other

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 reports the volume of procedures performed at ambulatory surgical centers (ASCs) in select categories reflecting typical high-volume categories of procedures. Although the Ambulatory Surgical Center Quality Reporting (ASCQR) Program currently contains some measures focused on cataract surgeries and colonoscopies, along with general urology and orthopedic measures, this measure under consideration (MUC) would capture the volume for many procedures previously not covered by the measure set. Measuring the volume of procedures relates to the program's goals of improving the safety and quality of outpatient procedures in ASCs.

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

Yes/No: Yes

Justification and Notes: There is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review (<u>Levaillant et al., 2021</u>) found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies. A similar review, focused on outpatient surgeries, also found a volume-outcome relationship across eight studies (<u>Stanak et al., 2020</u>).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This measure addresses a national trend where surgeries are moving from hospital settings to ASCs (MedPAC, 2019), and it leverages public reporting to help CMS and the public better understand possible quality differences between settings. This measure was previously in the ASCQR program, where it demonstrated a range in performance. Data from 2015 and 2016 demonstrates variation in performance in the number of procedures performed by facilities in the 25th and 75th percentiles across the condition categories. However, the number of procedures performed for each condition is 0 or close to 0 for facilities in the 50th percentile (using 2016 data) and for genitourinary and respiratory conditions, the number of procedures performed is 2 and 0, respectively, for facilities in the 75th percentile. This may indicate that some conditions demonstrate more variation than others.

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

Yes/No: Yes

PAGE 6 Ambulatory Surgical Center Quality Reporting Program

Justification and Notes: This measure was previously removed from the ASCQR program in CY2018 (see pp 59449 of the <u>Final Rule</u>), on the basis of the measurement burden outweighing the benefits to public reporting. However, electronic reporting of procedure volumes based on code lists should not be overly burdensome to ASCs, and the public reporting of specific procedure volumes may be useful to patients. In addition, MUC2022-030, Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (formerly OP-26), is submitted concurrently with this MUC, for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program. The specifications are aligned to facilitate comparisons of equivalent procedure volumes across ambulatory surgery centers and hospital outpatient departments, the key goal of the programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the measure developer, all data elements for this measure are in defined fields in electronic sources. ASCs can work from provided code sets to tabulate procedures performed in the prior calendar year using readily available electronic records; no abstraction is required. The measure was previously implemented in the program for six years, with facilities able to successfully report the measure.

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 developer has not submitted this measure for endorsement by a consensus-based entity (CBE); however, it is fully specified and the care setting and level of analysis match the program requirements. Because this is a structural measure simply tabulating procedure counts, concerns with the reliability and validity of the measure result are minimized; nevertheless, the developer has not conducted reliability or validity testing. Reliability testing could be conducted on the data elements to ensure procedures are being tabulated appropriately, and validity testing could be conducted to compare results on this measure to other measures in the ASCQR program to establish whether the measure result is correlated with other quality measures.

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: This measure was previously removed from the ASCQR program in CY2018 (see pp 59449 of the <u>Final Rule</u>), on the basis of the measurement burden outweighing the benefits to public reporting. However, at the time some commenters noted that the measure presented substantial value for public reporting, and others noted that the administrative burden for facilities should be minimal. No specific implementation issues have been identified.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

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Hospice High Priority Areas

Yes/No: NA

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group discussed voluntary reporting of the measure for critical access hospitals (CAHs) due to low case volume and noted that more complex surgical procedures do not occur in these facilities. The Rural Health Advisory Group also noted that all data elements are in defined fields and electronic sources, thus requiring no manual abstraction.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concerns regarding the use of volume as a proxy for quality, and mentioned that public reporting of the measure may negatively impact health equity (i.e., healthier patients who are able may travel out of rural areas to seek care). Additionally, the Health Equity Advisory Group suggested that demographic data should be collected to understand whether there are differences in populations that access and receive services from ASCs versus HOPDs.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

This measure reports the volume of procedures performed at ambulatory surgical centers (ASCs) in select categories reflecting typical high-volume categories of procedures. Although the Ambulatory Surgical Center Quality Reporting (ASCQR) Program currently contains some measures focused on cataract surgeries and colonoscopies, along with general urology and orthopedic measures, this measure under consideration (MUC) would capture the volume for many procedures previously not covered by the measure set. Measuring the volume of procedures relates to the program's goals of improving the safety and quality of outpatient procedures in ASCs.

This measure was previously removed from the ASCQR program in CY2018 (see pp 59449 of the Final Rule), on the basis of the measurement burden outweighing the benefits to public reporting. However, electronic reporting of procedure volumes based on code lists should not be overly burdensome to ASCs, and the public reporting of specific procedure volumes may be useful to patients. In addition, MUC2022-030, Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (formerly OP-26), is submitted concurrently with this MUC, for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program. The specifications are aligned to facilitate comparisons of equivalent procedure volumes across ambulatory surgery centers and hospital outpatient departments, the key goal of the programs.

MAP members expressed differing views on the value of volume data to patients. MAP members representing the patient perspective thought the measure would be useful to patients as they decide where to seek care, as one data point along with others (e.g., advice from providers). Other MAP members expressed concern about the value of volume data for informing patient decisions without other context, and encouraged the use of outcome measures instead.

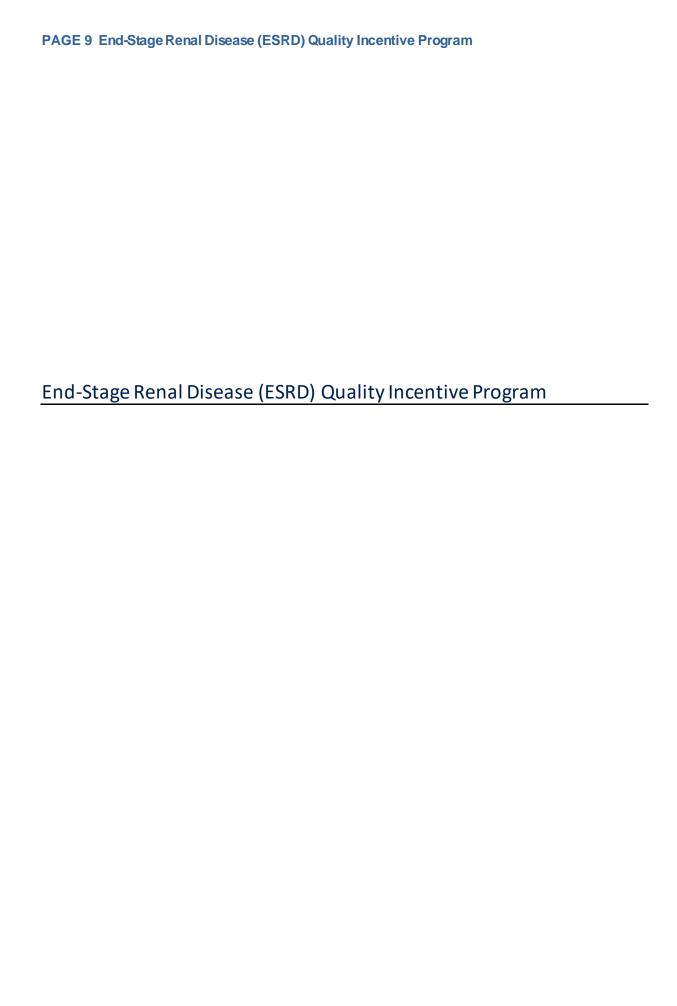
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Summary: What is the potential impact of this measure on quality of care for patients?

There is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review (<u>Levaillant et al., 2021</u>) found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies. A similar review, focused on outpatient surgeries, also found a volume-outcome relationship across eight studies (<u>Stanak et al., 2020</u>).

However, MAP discussed how there are varying levels of evidence for the correlation between the volume of procedures and outcomes depending on the procedure, and how the strength of the correlation varies by procedure as well. Some MAP members suggested limiting the measure to those procedures where volume has the strongest correlation with outcomes; however, they noted this would be a substantive change to the measure. Other MAP members did not support this change, as they thought the measure, as specified, could help to generate better data on the correlation between procedure volume and outcomes.

This measure addresses a national trend where surgeries are moving from hospital settings to ASCs (MedPAC, 2019), and it leverages public reporting to help CMS and the public better understand possible quality differences between settings. This measure was previously in the ASCQR program, where it demonstrated a range in performance. Data from 2015 and 2016 demonstrates variation in performance in the number of procedures performed by facilities in the 25th and 75th percentiles across the condition categories. However, the number of procedures performed for each condition is 0 or close to 0 for facilities in the 50th percentile (using 2016 data) and for genitourinary and respiratory conditions, the number of procedures performed is 2 and 0, respectively, for facilities in the 75th percentile. This may indicate that some conditions demonstrate more variation than others.



Preliminary Analysis – MUC2022-075 Standardized Modality Switch Ratio for Incident Dialysis Patients (SMoSR)

Measure Description:

The standardized modality switch ratio (SMoSR) is defined to be the ratio of numbers of observed modality switches (from in-center to home dialysis- peritoneal or home hemodialysis) that occur for adult incident ESRD dialysis patients treated at a particular facility, to the number of modality switches (from in-center to home dialysis- peritoneal or home hemodialysis) that would be expected given the characteristics of the dialysis facility's patients and the national norm of dialysis facilities. The measure includes only the first durable switch that is defined as lasting 30 continues days or longer.

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 under consideration (MUC) specifically addresses the End-Stage Renal Disease Quality Improvement Program (ESRD QIP) high priority area of Home Dialysis.

The literature suggests that patients prefer home or peritoneal dialysis, and that dialysis centers can adopt strategies such as a pre-dialysis education program to direct patients to home dialysis options consistent with their care preferences (<u>Jager et al.</u>, 2004 and <u>Goovaerts et al.</u>, 2005).

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

Yes/No: No

Justification and Notes: In the Spring 2022 review for consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3696), the Renal Standing Committee did not reach consensus on the evidence presented. Although the Committee agreed that encouraging the switch to home dialysis was consistent with patient preferences, and that the dialysis center could affect this clinical outcome by offering home dialysis and educating patients about this option, the Committee was concerned that facilities might be penalized for patients that preferred not to assume responsibility for their care at home, or where infrastructure limitations would prohibit home dialysis.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: In the Spring 2022 review for CBE endorsement, the Renal Standing Committee agreed a performance gap exists. In comprehensive testing of the measure result across all Medicarecertified dialysis facilities, the developer found median performance of 0.84, a 25th percentile of 0.37, and a 75th percentile of 1.52, indicating a wide range of 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: At present, there are no measures in the ESRD QIP that reflect patient preference for home dialysis. As the measure is fully applicable to every Medicare-certified dialysis

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facility, the measure result is useful to a broad population.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the developer, all data elements used to calculate the measure result are available in electronic sources, and the developer was able to successfully test the measure against the entire universe of possible facilities.

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: In the Spring 2022 review for CBE endorsement, the Renal Standing Committee did not pass the measure on validity, based on several concerns about the measure specifications and empiric validity data presented. As a result, the measure was not recommended for endorsement. These concerns include a weak correlation between this measure and a waitlisting measure, as well as risk of hospitalizations, insufficient exclusions (including patients who live alone and patients who elect not to receive home dialysis treatment), and missing comorbidities from the case mix adjustment model.

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 currently in use, and the developer did not raise any potential unintended consequences. In the Spring 2022 review for CBE endorsement, some members of the Renal Standing Committee raised a potential unintended consequence where practitioners might not encourage home dialysis to give dialysis facilities an opportunity to game the metric by then referring those patients back to home dialysis.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group shared that this is an important measure for rural health considerations, noting the underutilization of home dialysis services in rural communities.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group shared that the measure is important to health equity. The Health Equity Advisory Group expressed that racial disparities transcend socioeconomic status and that the measure would benefit from stratification. Additionally, the Health Equity Advisory Group highlighted a

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need to consider upstream factors which impact health.

Recommendation

Preliminary Analysis Recommendation:

Do Not Support for Rulemaking with Potential for Mitigation

The potential mitigation for this measure would be to address the concerns raised by the Renal Standing Committee regarding the evidence base and specifications, and validity, and resubmit the measure for endorsement by a consensus-based entity (CBE).

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

This measure under consideration (MUC) specifically addresses the End-Stage Renal Disease Quality Improvement Program (ESRD QIP) high priority area of Home Dialysis.

However, in the Spring 2022 review for endorsement by the consensus-based entity (CBE), the Renal Standing Committee did not pass the measure (National Quality Forum (NQF) #3696) on validity, based on several concerns about the measure specifications and empiric validity data presented. As a result, the measure was not recommended for endorsement. These concerns included a weak correlation between this measure and a waitlisting measure, as well as risk of hospitalizations, insufficient exclusions (including patients who live alone and patients who elect not to receive home dialysis treatment), and missing comorbidities from the case mix adjustment model. The Standing Committee also did not reach consensus on the evidence presented. Although the Committee agreed that encouraging the switch to home dialysis was consistent with patient preferences, and that the dialysis center could affect this clinical outcome by offering home dialysis and educating patients about this option, the Committee was concerned that facilities might be penalized for patients that preferred not to assume responsibility for their care at home, or where infrastructure limitations would prohibit home dialysis.

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

The literature suggests that patients prefer home or peritoneal dialysis, and that dialysis centers can adopt strategies such as a pre-dialysis education program to direct patients to home dialysis options consistent with their care preferences (<u>Jager et al., 2004</u> and <u>Goovaerts et al., 2005</u>).

In the Spring 2022 review for endorsement, the Renal Standing Committee reached agreed a performance gap exists. In comprehensive testing of the measure result across all Medicare-certified dialysis facilities (as many as 7,220), the developer found median performance of 0.84, a 25th percentile of 0.37, and a 75th percentile of 1.52, indicating a wide range of performance. This measure affects over 115,000 patients per year.

Preliminary Analysis – MUC2022-076 Standardized Fistula Rate for Incident Patients

Measure Description:

The Standardized Fistula Rate (SFR) for Incident Patients is based on the prior SFR (NQF #2977) that included both incident and prevalent patients. This measure was initially endorsed in 2016, but as part of measure maintenance review by the NQF Standing Committee in 2020, concerns were raised about the strength of evidence supporting the prior measure. Namely, recent updates to the KDOQI guidelines downgraded the evidence supporting fistula as the preferred access type and instead focus on catheter avoidance and developing an individualized ESKD Life plan.

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 under consideration (MUC) addresses the End-Stage Renal Disease Quality Improvement Program (ESRD QIP) high priority area of patient outcomes.

The MUC assesses the use of arteriovenous fistula (AVF) as the sole means of vascular access for maintenance hemodialysis patients. Guidelines by the National Kidney Foundation Disease Outcomes Quality Initiative (NKF KDOQI) suggest that fistula access is the preferred method, and is connected to improved clinical quality outcomes including lower rates of bloodstream infections (Lok et al., 2019).

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

Yes/No: No

Justification and Notes: As noted above, the KDOQI guidelines suggest that fistula access is preferable to alternatives, although these guidelines are generally based on low-quality evidence and expert opinion (Lok et al., 2019). The developer provided additional citations, including a finding that fistula access is associated with higher health-related quality of life and lower depression (Kim et al., 2020). However, in the Spring 2022 review for endorsement by the consensus-based entity (National Quality Forum (NQF) #3659), the Renal Standing Committee did not reach consensus on the evidence presented. Although the Committee agreed with the evidence presented that fistula access was preferable to alternatives, and that this intermediate clinical outcome would be affected by the dialysis center through initiatives such as patient education, the Committee was concerned about the strength of the evidence presented.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: In comprehensive testing of the measure result across 6,664 Medicare-certified dialysis facilities, the developer found median performance of 41.6 percent, a 25th percentile of 32.9 percent, and a 75th percentile of 49.9 percent, indicating variation in performance. The developer also found significant racial disparities, with a mean rate for White patients of 43.4 percent, and a mean rate for Black patients of 36.4 percent. However, in the Spring 2022 review for endorsement, the Renal Standing Committee did not reach consensus on the performance gap underpinning the measure result, with 62.5 percent of members voting "Low". The Standing Committee expressed concern with possible

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confounders affecting the performance gap, such as facility size, and insufficient case mix adjustment to account for patients for whom fistula access may not be appropriate based on their stage of care.

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 an existing and very similar measure already in the ESRD QIP, Hemodialysis Vascular Access: Standardized Fistula Rate (05641-C-ESRDQIP). The existing measure in the program lost endorsement in the Spring 2020 cycle, due to changes to the evidence base supporting the fistula rate. As the measure is fully applicable to every Medicare-certified dialysis facility, the measure result is useful to a broad population.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the developer, all data elements used to calculate the measure result are available in electronic sources, and the developer was able to successfully test the measure against the entire universe of possible facilities.

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 dialysis facilities, consistent with the ESRD QIP program structure. In the Spring 2022 review for CBE endorsement, the Renal Standing Committee did not review the measure for scientific acceptability as it had not passed the performance gap criterion. However, the Scientific Methods Panel reviewed both the reliability and validity testing to support the measure, rating both as "Moderate". A signal-to-noise reliability statistic showed 70.5 percent signal, and validity testing showed a convergent relationship between this MUC and measures of hospitalization and mortality.

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: A very similar measure is currently in use in the ESRD QIP, and no unintended consequences have been identified as a result. The developer did not identify any potential unintended consequences.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

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Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group shared that this is an important measure for rural health considerations, noting the underutilization of home dialysis services in rural communities.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group shared that the measure is important to health equity. The Health Equity Advisory Group expressed that racial disparities transcend socioeconomic status and that the measure would benefit from stratification. Additionally, the Health Equity Advisory Group highlighted a need to consider upstream factors which impact health.

Recommendation

Preliminary Analysis Recommendation:

Do Not Support for Rulemaking with Potential for Mitigation

The potential mitigation for this measure would be to address the concerns raised by the Renal Standing Committee regarding the evidence base and resubmit the measure for endorsement by a consensus-based entity (CBE).

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

This measure under consideration (MUC) addresses the End-Stage Renal Disease Quality Improvement Program (ESRD QIP) high priority area of patient outcomes. The MUC assesses the use of arteriovenous fistula (AVF) as the sole means of vascular access for maintenance hemodialysis patients. Guidelines by the National Kidney Foundation Disease Outcomes Quality Initiative (NKF KDOQI) suggest that fistula access is the preferred method, and is connected to improved clinical quality outcomes including lower rates of bloodstream infections (Lok et al., 2019).

This measure would replace an existing and very similar measure already in the ESRD QIP, Hemodialysis Vascular Access: Standardized Fistula Rate (05641-C-ESRDQIP). The existing measure in the program lost endorsement from the consensus-based entity (CBE) in the Spring 2020 cycle, due to changes to the evidence base supporting the fistula rate. As the measure is fully applicable to every Medicare-certified dialysis facility, the measure result is useful to a broad population.

MAP noted concerns that patients may choose not to pursue an arteriovenous fistula (AVF) and that the measure does not take patient preference into account.

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

As noted above, the KDOQI guidelines suggest that fistula access is preferable to alternatives, although these guidelines are generally based on low-quality evidence and expert opinion (Lok et al., 2019). The developer provided additional citations, including a finding that fistula access is associated with higher health-related quality of life and lower depression (Kim et al., 2020). However, in the Spring 2022 review for endorsement by the CBE (National Quality Forum (NQF) #3659, the Renal Standing Committee did not reach consensus on the evidence presented. Although the Committee agreed with the evidence presented that fistula access was preferable to alternatives, and that this intermediate clinical outcome would be affected by the dialysis center through initiatives such as patient education, the Committee was concerned about the strength of the evidence presented.

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In addition, the Renal Standing Committee did not reach consensus on the performance gap underpinning the measure result, with 62.5 percent of members voting "Low". The Standing Committee expressed concern with possible confounders affecting the performance gap, such as facility size, and insufficient case mix adjustment to account for patients for whom fistula access may not be appropriate based on their stage of care.

Preliminary Analysis – MUC2022-079 Standardized Emergency Department Encounter Ratio (SEDR) for Dialysis Facilities

Measure Description:

The Standardized Emergency Department Encounter Ratio is defined to be the ratio of the observed number of emergency department (ED) encounters that occur for adult Medicare ESRD dialysis patients treated at a particular facility to the number of encounters that would be expected given the characteristics of the dialysis facility's patients and the national norm for dialysis facilities. Note that in this document an emergency department encounter always refers to an outpatient encounter that does not end in a hospital admission. This measure is calculated as a ratio but can also be expressed as a rate.

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 under consideration (MUC) specifically addresses the Meaningful Measures 2.0 Healthcare Priorities of Chronic Conditions and Seamless Care Coordination, and the End-Stage Renal Disease Quality Improvement Program (ESRD QIP) high priority area of outcomes. The literature suggests that missed dialysis treatments are associated with a two-fold higher risk of an ED visit (<u>Cohen et al., 2020</u>) and 55 percent of all patients with ESRD visit the ED during their first year of dialysis (<u>Lovasik et al., 2016</u>).

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

Yes/No: Yes

Justification and Notes: This MUC is an outcome measure that is influenced by healthcare structures, as rates of ED visits by dialysis patients vary by dialysis schedule, with higher ED visit rates correlating with longer interdialytic intervals (Zhang et al., 2019). Another study found that nearly one-third of hospital admissions of ED origin among ESRD Medicare beneficiaries are for diagnoses that are dialysis related (Lovasik et al., 2016). According to the developer, dialysis facilities may also be able to prevent emergent ED visits and control medical costs with measures of the frequency of ED use, such as this MUC.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: In a three-year evaluation of over 6,500 facilities from 2014-2017, the distribution of SEDRs ranged from 0-4.30, with a mean of 1.00 and standard deviation of 0.34. This range of performance suggests variation in standardized ED visit rates across facilities for clinician groups and a gap in care that is evidence of a quality challenge. The MUC also considers disparities, as the developer provides data to identify performance gaps based on the following factors: gender, age (>75 years), and race (Hispanic, Asian, and Native American.)

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

Yes/No: Yes

Justification and Notes: At present, there are no measures in the ESRD QIP that reflect overall ED

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encounters among ESRD patients at dialysis facilities, however Standardized Hospitalization Ratio for Dialysis Facilities (National Quality Forum (NQF) #1463) assesses hospital admissions among dialysis patients. Additionally, Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505) and Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) (NQF #3566) are related measures as SEDR assesses the overall rate of ED use while ED30 focuses on ED utilization closely following a hospitalization. As the measure is fully applicable to every Medicare-certified dialysis facility, the measure result is useful to a broad population.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure uses data that is derived from an extensive national ESRD patient database, which is primarily based on facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Renal Management Information System (REMIS), the Medicare Enrollment Database (EDB), and Medicare claims data. Information on hospitalizations is obtained from Part A Medicare Inpatient Claims Standard Analysis Files (SAFs). There will be no additional data collection or submission burden for dialysis facilities or EDs.

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 endorsed by the consensus-based entity (NQF #3565), fully developed, and has been specified for the facility level of analysis. The developer conducted face validity and score-level empirical validity testing and focused on comparing the worse than expected SEDR group to all others. For reliability testing, the underlying signal to noise ratio of inter unit reliability (IUR) among approximately 6500 facilities across multiple years was consistently marginal (r=0.62 - 0.63), however, profile inter unit reliability (PIUR) was much higher (0.89 - 0.91), indicating more acceptable discrimination of outliers.

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 negative unintended issues to the patient have been identified and the developer does not provide any information regarding the benefits or harms of the measure.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

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The Rural Health Advisory Group shared that the measure is important, but expressed concerns about the need to travel for dialysis services in rural communities, which could create barriers to access.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group shared that the measure is important to health equity. The Health Equity Advisory Group expressed that the ability to stratify the measure is positive with regard to health equity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

At present, there are no measures in the End-Stage Renal Disease Quality Improvement Program (ESRD QIP) that reflect overall emergency department (ED) encounters among ESRD patients at dialysis facilities, however Standardized Hospitalization Ratio for Dialysis Facilities (National Quality Forum (NQF) #1463) assesses hospital admissions among dialysis patients. Additionally, Emergency Department Use without Hospital Readmission During the First 30 Days of Home Health (NQF #2505) and Emergency Department Encounters Occurring Within 30 Days of Hospital Discharge (ED30) (NQF #3566) are related measures as SEDR assesses the overall rate of ED use while ED30 focuses on ED utilization closely following a hospitalization. As the measure is fully applicable to every Medicare-certified dialysis facility, the measure result is useful to a broad population. In addition, the measure is endorsed by the consensus-based entity (NQF #3565).

MAP noted there may be some ED visits that are clearly not related to a patient's use of dialysis (e.g., for trauma or COVID-19), and asked whether the measure could exclude these visits. The developer agreed this is a challenging aspect of the measure but also explained that it is difficult to strike a balance between inclusivity and specificity when determining if an ED visit is related to dialysis complications. Overall, MAP was supportive of the measure as specified.

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

The literature suggests that missed dialysis treatments are associated with a two-fold higher risk of an ED visit (<u>Cohen et al., 2020</u>) and 55 percent of all patients with ESRD visit the ED during their first year of dialysis (<u>Lovasik et al., 2016</u>).

In a three-year evaluation of over 6,500 facilities from 2014-2017, the distribution of SEDRs ranged from 0-4.30, with a mean of 1.00 and standard deviation of 0.34. This range of performance suggests variation in standardized ED visit rates across facilities for clinician groups and a gap in care that is evidence of a quality challenge. The measure also considers disparities, as the developer provides data to identify performance gaps based on the following factors: gender, age (>75 years), and race (Hispanic, Asian, and Native American.)



Preliminary Analysis – MUC2022-018 Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)

Measure Description:

This electronic clinical quality measure (eCQM) provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of eligible CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in inpatient hospital care settings are eligible.

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 addresses safety and outcome eCQMs as priorities for the Hospital Inpatient Quality Reporting program, and the Safety Meaningful Measures 2.0 Healthcare Priority. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which increases the risk of cancer.

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

Yes/No: Yes

Justification and Notes: This is an intermediate-outcome electronic clinical quality measure (eCQM) using electronic health data at the facility level that provides a standardized method for monitoring the performance of diagnostic computed tomography (CT) scan radiation doses, a risk factor for cancer, while preserving image quality. According to evidence provided in the developer's submission for consensus-based entity (CBE) endorsement in 2021, CT scans are used in most acute care facilities, and statistical inference suggests these scans cause approximately 2 percent of all new U.S. cancers diagnoses every year (Berrington de Gonzalez et al, 2009). The developer cites a retrospective cohort study finding a threefold increase in leukemia and brain cancer for pediatric patients who were CT scanned (Pierce et al., 2012).

The developer cites a randomized clinical trial of two interventions designed to reduce CT doses, finding "detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduced doses, particularly organ doses" (Smith-Bindman et al., 2020).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This measure addresses a patient safety concern of increased radiation dose from CT exams, as well as limited image quality of CT exams. The developer notes that doses used for CT vary substantially across imaging facilities for patients imaged for the same clinical indication. Specifically, the developer notes a study of 151 imaging facilities and hospitals where, after adjusting for patient characteristics, abdominal CT exams had a four-fold range in mean effective radiation dose and a

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17-fold range in the proportion of high dose exams (<u>Smith-Bindman et al., 2019</u>). The developer does not argue that there is a persistent quality challenge in image quality for CT scans; rather, this component of the measure is included as a "balancing" element, to prevent an unintended consequence where an excessive reduction in CT doses might compromise image quality and the diagnostic process.

In testing at 16 hospitals, the developer found mean performance at 31 percent, with a standard deviation of 18 percent, and minimum and maximum rates of one and 90 percent, respectively, indicating wide variation in performance and a substantial performance gap. For this measure, a lower score indicates better quality.

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

Yes/No: Yes

Justification and Notes: Though there are several other measures focused on patient safety in the Hospital Inpatient Quality Reporting (IQR) program, none assess radiation dosage or other risks associated with cancer. The measure is being concurrently submitted for rulemaking in the Hospital Outpatient Quality Reporting (OQR) program, as well as the Merit-based Incentive Payment System (MIPS) program, encouraging alignment across these settings and across two otherwise separate levels of analysis. Reporting on this measure is applicable to a broad population: over a third of acute care hospitalizations involved at least one CT scan (Vance et al., 2013).

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure is an eCQM and according to the developer, all data elements are in defined fields in electronic sources. The developer conducted a feasibility assessment across seven different EHR systems at 15 different hospital sites, finding all data elements were available in structured fields, and the measure had no impact on clinician workflow. The National Quality Forum's Patient Safety Standing Committee rated the measure "High" for feasibility in its fall 2021 evaluation.

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 endorsed by a consensus-based entity (CBE) (NQF #3663e), is fully developed, and measure testing has demonstrated reliability and validity for the level of analysis. The measure was tested for reliability through a split-half correlation intraclass correlation coefficient (ICC), yielding a score of 0.99, indicating high reliability. NQF's Scientific Methods Panel and Patient Safety Standing Committee both rated the measure "High" for reliability in the fall 2021 evaluation by a. Likewise, both rated the measure "High" for validity in the same evaluation, based on a face validity assessment of a Technical Expert Panel (TEP) composed of both clinicians and patient advocates.

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 developer identified a possible unintended consequence, suggesting that image quality of CT scans might deteriorate if the radiation dose was lowered. The developer notes that

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by specifying the measure to also capture CT exams reported as having low image quality, the incentives are aligned to produce CT scans that are within an appropriate range that balances safety considerations with image quality.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns regarding data collection.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The measure addresses safety and outcome eCQMs as priorities for the Hospital Inpatient Quality Reporting program, and the Safety Meaningful Measures 2.0 Healthcare Priority. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which increases the risk of cancer. Though there are several other measures focused on patient safety in the Hospital Inpatient Quality Reporting (IQR) program, none assess radiation dosage or other risks associated with cancer. The measure is being concurrently submitted for rulemaking in the Hospital Outpatient Quality Reporting (OQR) program, as well as the Merit-based Incentive Payment System (MIPS), encouraging alignment across these settings and across two otherwise separate levels of a nalysis. The measure is endorsed by a consensus-based entity (CBE) (National Quality Forum #3663e). Reporting on this measure is applicable to a broad population: over a third of acute care hospitalizations involved at least one CT scan (Vance et al., 2013).

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

This is an intermediate-outcome electronic clinical quality measure (eCQM) using electronic health data at the facility level that provides a standardized method for monitoring the performance of diagnostic computed tomography (CT) scan radiation doses, a risk factor for cancer, while preserving image quality. According to evidence provided in the developer's submission for consensus-based entity (CBE) endorsement in 2021, CT scans are used in most acute care facilities, and statistical inference suggests these scans cause approximately 2 percent of all new U.S. cancers diagnoses every year (Berrington de Gonzalez et al, 2009). The developer cites a retrospective cohort study finding a threefold increase in

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leukemia and brain cancer for pediatric patients who were CT scanned (Pierce et al., 2012).

The developer notes that doses used for CT vary substantially across imaging facilities for patients imaged for the same clinical indication. Specifically, the developer notes a study of 151 imaging facilities and hospitals where, after adjusting for patient characteristics, abdominal CT exams had a four-fold range in mean effective radiation dose and a 17-fold range in the proportion of high dose exams (Smith-Bindman et al., 2019). The developer cites a randomized clinical trial of two interventions designed to reduce CT doses, finding "detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduced doses, particularly organ doses" (Smith-Bindman et al., 2020).

Preliminary Analysis – MUC2022-032 Geriatrics Surgical Measure

Measure Description:

This programmatic measure assesses hospital commitment to improving surgical outcomes for patients greater than or equal to 65 years of age through patient-centered competencies aimed at achieving quality of care and safety for all older adult surgical patients. The measure will include 11 attestation-based questions across 7 domains representing a comprehensive framework required for optimal care of the older surgical patient. A hospital will receive a point for each domain where they attest to all items from at least one question (for a total of 7 points). Note that "patients" in all elements refers to surgical patients greater than or equal to 65 years of age at time of operation.

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 under consideration (MUC) specifically addresses several Hospital Inpatient Quality Reporting (Hospital IQR) Program high priority areas for future measure consideration, including Care Coordination, Safety, and Health Equity. It is a programmatic measure that consists of structural and process measures which, according to the developer, address all six Institute of Medicine domains (safe, effective, patient-centered, timely, efficient, equitable), and is comprehensive across the full spectrum of geriatric surgical care. This MUC addresses a critical patient population, older patients with complex medical, physiological, and psychosocial needs. The developer notes that based on 2019 US Census data, the 65-and-older population grew by over a third since 2010, and by 2030 this population is estimated to grow to 72 million (20 percent of the total population).

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

Yes/No: No

Justification and Notes: The developer describes this measure as a programmatic measure that assesses provider infrastructure. The measure proposes a holistic approach to capture the care pathway for this unique population using provider attestation. The measure includes 11 attestation-based question across seven domains representing a comprehensive framework required for optimal care of the older surgical patient. A hospital will receive a point for each domain where they attest to at least one corresponding statement (for a total of seven points).

The developer presented literature to support an association between the processes and structures assessed by this MUC and clinical outcomes; however, it is not clear how attestation based on this measure will directly lead to improved patient outcomes.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: Across an unspecified number of sites, the average performance was hospitals attesting to having met 6 out of the 7 domains. The median score was 5 out of 7 domains, minimum was 0 and maximum was 7. This does not indicate much room for improvement; however, without knowing more about the sites that provided this data, it is hard to interpret this information.

The developer does provide citations from the literature indicating there are performance gaps for the

individual domains of care.

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 developer proposes that this type of programmatic facility-level geriatric measure incentivizes team-based care organized around the geriatric surgical patient to meet the challenges unique to geriatric surgical patients. The developer further states that although existing quality metrics have improved both the rate and reporting of clinical outcomes (falls, appropriate use of anticoagulants, etc.) that are important to older individuals, these measures can be narrow in scope and may have limited long term effectiveness due to ceiling effects.

The developer has submitted MUC2022-112 Geriatrics Hospital Measure concurrently with this MUC, also for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program. The attestation elements are similar across the two measures, although there are some variations and the Geriatrics Hospital Measure has more questions than the MUC (Geriatrics Surgical Measure). Implementing both measures applies the holistic framework to both older surgical patients and older patients who are admitted to the hospital or seen in the emergency department.

Can the measure be feasibly reported?

Yes/No: No

Justification and Notes: The developer notes that the measure includes some data elements that are in defined fields in electronic sources. The measure is submitted by attestation. This attestation would be done using a web-based tool within the HQR system. The developer indicates a workflow analysis was conducted; however, the results of that analysis are not presented, and it is reasonable to assume the data collection effort to reliably collect data on over seven domains of facility processes and structures is at least somewhat labor intensive.

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 for the hospital/facility/agency level of analysis and care setting. Reliability testing was provided by the developer noting a Test-Retest Kappa, Interrater Reliability (IRR) of 0.98. The developer conducted a face validity assessment using a Modified Delphi Method, although the developer did not provide specific results broken out by the group of experts or patients/caregivers that were voting on the validity of the measure result. The measure has not been submitted for endorsement by a consensus-based entity (CBE), nor has the measure been reviewed by MAP in prior review cycles.

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 currently in use. The developer advanced a possible unintended consequence related to the encouragement of ambulation, which may inadvertently increase the rate of falls.

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PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed that while this is an important measure, rural providers do not have a large pool to hire clinicians which results in an ever-rotating staff of locums. Thus, rural health providers may be at a disadvantage for producing consistent documentation and reporting for measure compliance. The Rural Health Advisory Group expressed concern that there are limited social services resources in rural settings, thereby impacting one of the attestation questions included in the measure. The Rural Health Advisory Group expressed concern that public reporting of the measure could result in erosion of community trust. Finally, the Rural Health Advisory Group noted that the measure is applicable across settings (i.e., includes the correct processes to take care of an older adult).

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed that geriatric patients are more fragile and emphasized the importance of assessing their needs. The Health Equity Advisory Group was not opposed to the concept of the measure, but cited concerns regarding implementation and limited evidence that attestations lead to improved patient outcomes or further health equity.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional pending endorsement by a consensus-based entity (CBE), and further work on paring down the elements included in the attestation, and presenting information about gaps for the components covered by the measure.

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

This measure under consideration (MUC) specifically addresses several Hospital Inpatient Quality Reporting (Hospital IQR) Program high priority areas for future measure consideration, including Care Coordination, Safety, and Health Equity. The developer describes this measure as a programmatic measure that assesses provider infrastructure. The measure proposes a holistic approach, using provider attestation, to capture the care pathway for a critical patient population, older patients with complex medical, physiological, and psychosocial needs The measure includes 11 attestation-based questions across seven domains representing a comprehensive framework required for optimal care of the older surgical patient. A hospital will receive a point for each domain where they attest to at least one corresponding statement (for a total of seven points).

While MAP supported the measure concept, there was discussion about difficulties with the attestation portion of the measure. MAP supported the importance of a measure focused on older adults as a

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vulnerable population, and noted how attestation measures can help to build out the infrastructure for and direct attention to important topics. However, MAP members also expressed concern about the subjectiveness of attestation-based measures, with some noting a preference for outcome or process measures. MAP also noted the overlap with MUC2022-112 Geriatrics Hospital Measure.

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

The developer notes that based on 2019 <u>US Census data</u>, the 65-and-older population grew by over a third since 2010, and by 2030 this population is estimated to grow to 72 million (20 percent of the total population). Across an unspecified number of sites, the average performance was hospitals attesting to having met 6 out of the 7 domains. The median score was 5 out of 7 domains, the minimum was 0 and the maximum was 7. This does not indicate much room for improvement; however, the measure developer noted that sites participating in testing may not be representative of all hospitals.

The developer does provide citations from the literature indicating there are performance gaps for the individual domains of care. The developer also presented literature to support an association between the processes and structures assessed by this measure and clinical outcomes; however, it is not clear how attestation based on this measure will directly lead to improved patient outcomes.

Preliminary Analysis – MUC2022-055 Hybrid Hospital-Wide All-Cause Risk Standardized Readmission Measure

Measure Description:

Hospital-level, risk-standardized readmission rate (RSRR) of all-cause 30-day unplanned readmission after admission for any eligible condition within 30 days of hospital discharge. The measure, based on NQF #2879, uses enrollment data, inpatient claims, and electronic health record data. Hospitals receive a single summary RSRR, derived from the volume-weighted results of five specialty cohorts. Conditionally supported by the MAP pending NQF endorsement and currently in the IQR Program (voluntary reporting 7/1/2021, mandatory reporting beginning 7/1/2023). This MUC submission expands the cohort from Medicare fee-for-service (FFS) patients to include Medicare Advantage patients age 65 & older.

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: A previous version of this measure was considered by the Measure Applications Partnership (MAP) during the 2014-2015 pre-rulemaking cycle and was encouraged to continue development. That version of the measure has since received endorsement from the consensus-based entity (National Quality Forum (NQF) #2879) and is currently in the Hospital Inpatient Quality Reporting (IQR) program (voluntary reporting 7/1/2021, mandatory reporting beginning 7/1/2023). This MUC submission expands the cohort of that existing measure from Medicare fee-for-service (FFS) patients to include Medicare Advantage (MA) patients ages 65 and older. This expanded measure addresses the high priority areas of communication/care coordination and effective prevention and treatment practices in the Hospital IQR program. Additionally, it addresses the Meaningful Measures 2.0 goal to prioritize outcome measures.

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

Yes/No: Yes

Justification and Notes: This outcome measure estimates a hospital-level 30-day risk-standardized readmission rate (RSRR). Readmission following hospitalization is a costly and often preventable event. Between July 2011 and June 2012, almost one-sixth of Medicare beneficiaries — more than 1.1 million patients — were readmitted within 30 days of discharge from an acute care hospital. Randomized controlled trials have shown that improvement in the following areas can directly reduce readmission rates: quality of care during the initial admission; improvement in communication with patients, their caregivers, and their clinicians; patient education; pre-discharge assessment; and coordination of care after discharge. Evidence that hospitals have been able to reduce readmission rates through quality-of-care initiatives illustrates the degree to which hospital practices can affect readmission rates.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This measure was developed to identify institutions whose performance is better or worse than would be expected based on their patient case mix and hospital service mix, and therefore promote hospital quality improvement and better inform consumers about care quality.

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Between July 2012 and June 2013, RSRRs ranged from 11.0 to 21.4 percent (median: 15.5 percent) among 4,772 hospitals. This variation in performance indicates a quality gap.

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 expands the cohort of an existing measure to include MA patients in addition to Medicare FFS patients. The expansion allows for the addition of several million admissions to improve the reliability of the measure and expand the population to better represent all Medicare beneficiaries in quality measures. The measure is intended to complement the existing CMS Hospital-Wide All-Cause Risk-Standardized Mortality Measure (CMIT 06031-C-HIQR) to allow assessment of trends in hospital performance for both outcomes, similar to other complementary pairs of readmission and mortality measures for specific conditions and procedures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure uses Medicare beneficiary enrollment data, claims data, and electronic health record (EHR) data. All critical data elements used in the measure are included in the core clinical data elements (CCDEs). The CCDE are a set of 21 HER data elements that are captured on most adults admitted to acute care hospitals, are easily extracted from EHRs, and can be used to risk adjust hospital outcome measures for a variety of conditions and procedures. Administrative claims data used in this measure are routinely captured as part of the billing process and no fees are associated with data collection. The measure is reported to the program through claims and EHR clinical data for risk adjustment. The developer does not anticipate an increase in hospital burden as a result of increasing the cohort size to include MA admissions.

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: MUC2022-055 is based on NQF #2879 and is fully developed and tested at the facility-level of analysis in the hospital inpatient facility setting. The population of the endorsed measure specification is Medicare FFS patients who are 65 years or older and experience readmission within 30 days of hospital discharge. MUC2022-055 expands the cohort to include MA patients in addition to Medicare FFS patients. The developer conducted reliability and validity testing of the revised measure using claims and found the measure to have strong reliability and that the measure was moderately, negatively correlated with other measures of hospital quality (as expected).

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: A prior version of this measure is currently in use in the Hospital IQR program with a voluntary reporting period from July 2021 to June 2022 and a mandatory reporting period from July 2023 to June 2024. According to the developer, no unintended consequences to the patient were identified during measure development, testing, or use. The developer also notes that potential

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unintended consequences should be monitored over time, such as the inappropriate shifting of care or coding/billing practices, or increased patient morbidity and mortality.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group noted that the measure is expanded to include Medicare Advantage patients (in addition to Medicare fee-for-service (FFS) patients) and expressed that this would improve the ability of rural health providers to report data to CMS. The Rural Health Advisory Group also highlighted that Medicare Advantage enrollees comprise a large proportion of rural patient populations.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group discussed that the measure is a re-specification of the current measure, which is stratified for hospitals. Results of the current measure are provided confidentially by dual-eligibility, race, and ethnicity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The goal of this fully developed, outcome-based measure is to improve patient outcomes by providing patients, physicians, hospitals, and policymakers with information about hospital-level, risk-standardized all-cause unplanned readmission rates. A previous version of this measure was considered by the Measure Applications Partnership (MAP) during the 2014-2015 pre-rulemaking cycle and was encouraged to continue development. That version of the measure has since received endorsement from the consensus-based entity (National Quality Forum (NQF) #2879) and is currently in the Hospital Inpatient Quality Reporting (IQR) program (voluntary reporting 7/1/2021, mandatory reporting beginning 7/1/2023). This MUC submission expands the cohort from Medicare fee-for-service (FFS) patients to include Medicare Advantage (MA) patients ages 65 and older. Additionally, the measure addresses the high-priority areas of communication/care coordination, effective prevention, and treatment practices in the Hospital IQR program. Lastly, this measure complements the existing Centers for Medicare & Medicaid Services (CMS) Hospital-Wide All-Cause Risk-Standardized Mortality Measure (CMIT 06031-C-HIQR) to allow assessment of trends in hospital performance for both outcomes.

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

Readmission following hospitalization is a costly and often preventable event. Between July 2011 and June 2012, almost one-sixth of Medicare beneficiaries – more than 1.1 million patients – were

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readmitted within 30 days of discharge from an acute care hospital. Between July 2012 and June 2013, the risk-standardized readmission rates (RSRRs) ranged from 11.0 to 21.4 percent (median: 15.5 percent) among 4,772 hospitals. This variation in performance indicates a quality gap.

Preliminary Analysis – MUC2022-057 Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure

Measure Description:

Hospital-level, risk-standardized 30-day all-cause mortality rate (RSMR) for Medicare fee-for-service (FFS) and Medicare Advantage (MA) patients (65 to 94). The measure, based on NQF #3502, uses enrollment data, inpatient claims, and electronic health data to identify 30-day all-cause mortality outcome, and adjust for comorbidities based on the ICD-10 diagnosis/procedure codes and clinical risk factors from electronic health data for the measure score calculation. This measure, previously conditionally supported for use in IQR and planned for use by CMS for voluntary reporting in IQR, is being expanded to include Medicare Advantage patients in addition to FFS patients in the cohort.

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: A previous version of this measure was considered by the Measure Applications Partnership (MAP) during the 2017-2018 pre-rulemaking cycle and was conditionally supported pending NQF endorsement. That version of the measure has since received endorsement from the consensus-based entity (National Quality Forum (NQF) #3502) and is planned for use by the Centers for Medicare & Medicaid Services (CMS) for voluntary reporting in the Hospital Inpatient Quality Reporting (IQR) program. This MUC submission expands the cohort from Medicare fee-for-service (FFS) patients to include Medicare Advantage (MA) patients ages 65 and older. The measure addresses the high priority areas of effective prevention and treatment practices and safety in the Hospital IQR program. Additionally, it addresses the Meaningful Measures 2.0 goal to prioritize outcome measures.

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

Yes/No: Yes

Justification and Notes: This outcome measure estimates a hospital-level 30-day risk-standardized mortality rate (RSMR). Mortality is an outcome that is meaningful to patients and providers. Estimates suggest that more than 400,000 patients die annually from preventable harm in hospitals (<u>James, 2013</u>) Multiple organizations, including the <u>Institute for Healthcare Improvement (IHI)</u>, promote a range of evidence-based strategies to reduce hospital mortality. These strategies include: adoption of strategies to reduce ventilator-associated pneumonia; delivery of reliable, evidence-based care for acute myocardial infarction; and prevention of adverse drug events, central line infections, and surgical site infections.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer provides data from July 2016 to June 2017 which include 10 million inpatient admissions among Medicare FFS beneficiaries between the ages of 65 and 94 at 4,700 U.S. hospitals. Compared to the median (RSMR of 6.93 percent), some hospitals perform substantially better with lower overall risk-standardized 30-day all-cause mortality rate (RSMR of 3.95 percent) than the average-performing hospital, while other hospitals are performing substantially worse (RSMR of 8.70 percent) than the average performer. This variation in performance demonstrates a quality gap.

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 expands the cohort of an existing measure to include MA patients in addition to Medicare FFS patients. The expansion allows for the addition of several million admissions to improve the reliability of the measure and expand the population to better represent all Medicare beneficiaries in quality measures. The measure is intended to complement the existing CMS Hospital-Wide All-Cause Risk-Standardized Readmission Measure (02701-C-HIQR) to allow assessment of trends in hospital performance for both readmission and mortality outcomes, similar to other complementary pairs of readmission and mortality measures for specific conditions and procedures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure uses Medicare beneficiary enrollment data, claims data, and electronic health record (EHR) data. All critical data elements used in the measure are included in the core clinical data elements (CCDEs). The CCDE are a set of 21 EHR data elements that are captured on most adults admitted to acute care hospitals, are easily extracted from EHRs, and can be used to risk adjust hospital outcome measures for a variety of conditions and procedures. Administrative claims data used in this measure are routinely captured as part of the billing process and no fees are associated with data collection. The measure is reported to the program through claims EHR clinical data for risk adjustment. The developer does not anticipate an increase in hospital burden as a result of increasing the cohort size to include MA admissions.

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: MUC2022-057 is based on NQF #3502 and is fully developed and tested at the facility-level of analysis in the hospital inpatient facility setting. The population of the endorsed measure specification is Medicare FFS patients between the ages of 65 and 94 who experience death from any cause within 30 days after the index admission date. MUC2022-057 expands the cohort to include MA patients in addition to Medicare FFS patients. The developer conducted reliability and validity testing of the revised measure. Using a data set with matched administrative claims and EHR data, the developer found the measure to have strong reliability. Using a claims-only version of the measure, the developer reported a trend toward better performance on the MUC with better performance on three comparator measures, as expected.

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: A prior version of this measure is currently in use in the Hospital IQR program with a voluntary reporting period from July 2022 to June 2023. During the 2017-2018 pre-rulemaking review of the prior version of this measure, MAP raised concerns about potential unintended consequences such as delayed referrals to hospice or palliative care, or increased rates of unnecessary interventions at the end of a person's life. According to the developer, no unintended consequences to

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the patient were identified during measure development, testing, or use. The developer also notes that potential unintended consequences should be monitored over time, such as the inappropriate shifting of care or coding/billing practices, or increased patient morbidity and mortality.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group noted that the measure is expanded to include Medicare Advantage patients (in addition to Medicare fee-for service (FFS) patients) and expressed that this would improve the ability of rural health providers to report data to CMS. The Rural Health Advisory Group also highlighted that Medicare Advantage enrollees comprise a large proportion of rural patient populations.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group discussed expanding the denominator of the measure, particularly with regard to managed care. The Health Equity Advisory Group expressed that the measure (in addition to MUC2022-055) should be prioritized for stratification by race and ethnicity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The goal of this fully developed, outcome-based measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about hospital-level, risk-standardized mortality rates (RSMRs) following hospitalization for a range of medical conditions and surgical procedures. A previous version of this measure was considered by the Measure Applications Partnership (MAP) during the 2017-2018 pre-rulemaking cycle and was conditionally supported pending endorsement by the consensus-based entity (CBE). That version of the measure has since received endorsement (National Quality Forum (NQF) #3502) and is planned for use by the Centers for Medicare & Medicaid Services (CMS) for voluntary reporting in the Hospital Inpatient Quality Reporting (IQR) program.

This MUC submission expands the cohort from Medicare fee-for-service (FFS) patients to include Medicare Advantage (MA) patients ages 65 and older. Additionally, the measure addresses the high priority areas of effective prevention and treatment practices, and safety in the Hospital IQR program. By measuring hospital-wide mortality (HWM), CMS can ensure that efforts to reduce other outcomes, such as readmission and resource utilization, are not resulting in unintended consequences. Lastly, this HWM measure complements the existing CMS Hospital-Wide All-Cause Risk-Standardization Readmission Measure (02701-C-HIQR) to allow assessment of trends in hospital performance for both

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outcomes.

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

More than 400,000 patients die annually from preventable harm in hospitals. The developer provides data from July 2016 to June 2017 which include 10 million inpatient admissions among Medicare FFS beneficiaries between the ages of 65 and 94 at 4,700 U.S. hospitals. Compared to the median (RSMR of 6.93 percent), some hospitals perform substantially better with lower overall RSMR (RSMR of 3.95 percent) than the average-performing hospital, while other hospitals are performing substantially worse (RSMR of 8.70 percent) than the average performer. This variation in performance demonstrates a quality gap.

Preliminary Analysis – MUC2022-058 Hospital Disparity Index (HDI)

Measure Description:

The HDI is a prototype method for a single score that summarizes several measurements of disparity in care at a hospital. This score will summarize existing results of the Centers for Medicare and Medicaid Services (CMS) Disparity Methods (stratified measure results) across a range of measures and social and demographic risk factors, to provide more accessible information about variations in healthcare disparity across hospitals.

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 under consideration (MUC) addresses Health Equity, a stated high-priority area for measurement for the Hospital Inpatient Quality Reporting Program (IQR), as well as a Meaningful Measures 2.0 priority (Equity). At present, there are no other measures in the Hospital IQR program that calculate disparities in quality of care based on race and ethnicity, or dual-eligible status.

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

Yes/No: Yes

Justification and Notes: This MUC reports, in a combined score, both the Within-Hospital Disparity (the difference in readmission rates between dual-eligible and non-dual-eligible patients at a given hospital), and the Across-Hospital Disparity (the readmission rate at a given hospital for dual-eligible patients only), for all seven component readmission measures currently implemented in federal programs. Details of this methodology, including recent statistical findings, the risk- and case mix-adjustment process, and the expert panel review process, are available in the CMS Publication 2021 Disparity Methods Updates and Specifications Report. In addition to the current dual-eligible status, this MUC proposes to add an additional factor for identifying disparities: race and ethnicity.

Hospital readmissions rates have a clear relationship to healthcare processes and structures. In the 2018 endorsement renewal submission to the consensus-based entity (National Quality Forum (NQF) #1789), one of the component measures included in the analysis described above, several steps hospitals can take to reduce readmissions rates are described and cited, including medication reconciliation, patient education, verifications prior to discharge, and improving communication between providers during care transitions.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer submitted performance data finding "strong variation between the best and worst performing hospitals" on the measure, with a maximum performance of 2.35, minimum performance of -2.82, and a standard deviation of 0.33. The aggregate findings of the confidential reporting for a similar measure focused on disparities for dual-eligible patients found a significant variation in quality of care across the thousands of hospitals studied. Most hospitals had a statistically significant higher rate of readmissions for dual eligible beneficiaries. In the literature, racial and ethnic disparities in readmissions rates are well-established (Joynt et al., 2011); as well, in a 2014

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analysis of risk-standardized readmissions rates, <u>CMS found disparities</u> in readmission rates based on the proportion of Medicaid patients, and the proportion of black patients. Hospital readmissions have both a significant effect on the health and well-being of patients, as well as tens of billions of dollars in cost to the federally funded health care system (<u>AHRQ 2014</u>). Taken together, performance data on the measure and published findings of disparities in readmission rates suggest a quality challenge.

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 MUC is a summary score representing the combined results of all six readmission measures in the Hospital Readmissions Reduction Program (HRRP), and the Hospital-Wide All-Cause Unplanned Readmission Measure in the Hospital IQR program. However, because this composite measure reports only the disparities in rates, and not the rates themselves, the information captured by the measure result is entirely different, so the measure is not duplicative. At present, a similar measure (disaggregated disparity in readmission rates for each of the seven measures in the composite MUC) is currently confidentially reported to hospitals on an annual basis as part of the Hospital IQR program preview reports.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This MUC is a composite of seven measures already reported to CMS as part of the Hospital IQR and HRRP programs. At present, a similar measure (disaggregated disparity in readmission rates for each of the seven measures in the composite MUC) is currently confidentially reported to hospitals on an annual basis as part of the Hospital IQR program preview reports. Hospitals would not have to conduct any additional data collection to report on the measure.

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 developer has not yet submitted this measure for endorsement by a consensus-based entity (CBE); however, the measure is fully developed, and reflects the appropriate care setting, level of analysis, and population for the program. Although reliability has been established in the component measures as part of the endorsement process by the consensus-based entity (CBE), reliability testing at the measure score level has not been conducted. According to NQF's 2021 Measure Evaluation Criteria and Guidance, reliability testing should be conducted at the composite score level. In addition, validity testing has not 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 developer raises a potential unintended consequence: that facilities may have difficulty interpreting the single summary score. However, the developer indicates that the presentation strategy will reflect the need for additional explanation; if the feedback reports that provide scores for the fourteen individual factors that would constitute this summary score (two

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disparity factors across each of seven readmission measures), that would provide sufficient explanation for hospitals. An additional possible unintended consequence is confusion for patients and family caregivers if the measure is publicly reported, who may also struggle to interpret the single score and may not benefit from the detailed feedback reports and methodological details supporting the composite construction. Although the confidential reports for individual hospital performance are not currently publicly reported, all measures formally included in the Hospital IQR program as quality measures are publicly reported; if included in rulemaking, this measure may also potentially be publicly reported.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group cited potential reporting challenges. The Rural Health Advisory Group expressed that some patients may distrust questions regarding SDOH and/or refuse services.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group cited concerns that a composite measure such as this could mask health disparities. The Health Equity Advisory Group also raised concerns about the dual eligible rates.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, including testing with low-volume hospitals that do not have all seven readmission rates calculated and may have small numbers of the targeted groups, and endorsement by a consensus-based entity (CBE).

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

This measure under consideration (MUC) addresses Health Equity, a stated high-priority area for measurement for the Hospital Inpatient Quality Reporting Program (IQR), as well as a Meaningful Measures 2.0 priority (Equity). At present, there are no other measures in the Hospital IQR program that calculate disparities in quality of care based on race and ethnicity, or dual-eligible status. These areas of disparities are of paramount importance for the many millions of people belonging to groups that have been historically marginalized. However, the measure has not been tested for reliability or validity.

MAP expressed concerns that the measure title may be misleading, as the measure is a composite of readmissions measures only, and recommended renaming the measure to focus on readmissions. Some MAP members also expressed concern with only focusing on readmission measures. While MAP supported the intent of the measure, to identify and reduce disparities, some MAP members asked that

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CMS provide confidential reports of the composite measure score to hospitals before making the reports publicly available. MAP also discussed the importance of seeking patient feedback on the composite measure, and suggested as the measure evolves, that the measure developer involve patients in reviewing the measure.

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

Disparities in quality of care based on race and ethnicity and dual-eligible status are well established in the literature, and are reflected in contemporary analyses of hospital performance on the currently implemented measures of readmission in the Hospital IQR program and the Hospital Readmissions Reduction Program (HRRP). Addressing these disparities by reducing hospital readmissions for these groups would have a substantial positive impact on the health and well-being on of potentially millions of patients every year, in addition to representing a substantial cost savings. Hospitals can reduce readmissions rates using several interventions, including medication reconciliation, patient education, verifications prior to discharge, and improving communication between providers during care transitions.

Preliminary Analysis – MUC2022-112 Geriatrics Hospital Measure

Measure Description:

This structural measure assesses hospital commitment to improving outcomes for patients greater than or equal to 65 years of age through patient-centered competencies aimed at achieving quality of care and safety for all older patients. The measure will include 14 attestation-based questions across 8 domains representing a comprehensive framework required for optimal care of older patients admitted to the hospital or being evaluated in the emergency department. A hospital will receive a point for each domain where they attest to at least one corresponding statement (for a total of 8 points). For each item, attestation of all elements is required to qualify for the measure numerator.

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 under consideration (MUC) specifically addresses the Hospital Inpatient Quality Reporting Program (HIQR) high-priority areas of Care Coordination, Safety, and Health Equity. The patient population targeted by the optimal care framework advanced by this measure is older patients with complex care needs. According to the <u>US Administration on Aging (AoA)</u>, people age 65 years and older represent 16 percent of the population today, rising to nearly 22 percent by 2040. The report also underscores that nearly a quarter of these assessed their own health as fair or poor, with most older Americans having at least one chronic condition such as arthritis, heart disease, or cancer, and 40 percent having difficulty with mobility.

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

Yes/No: No

Justification and Notes: The developer describes this measure as a programmatic measure that assesses provider infrastructure. The measure proposes a holistic approach to capture the care pathway for this unique population using provider attestation. The measure includes 14 attestation-based question across eight domains representing a comprehensive framework required for optimal care of older patients admitted to the hospital or being evaluated in the emergency department. A facility will receive a point for each domain where they attest to at least one corresponding statement (for a total of eight points).

The developer presented literature to support an association between the processes and structures assessed by this MUC and clinical outcomes; however, it is not clear how attestation based on this measure will directly lead to improved patient outcomes.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: Across an unspecified number of sites, the average performance was hospitals attesting to having met 7 out of the 8 domains of optimal care for older patients. This does not indicate much room for improvement; however, without knowing more about the sites that provided this data, it is hard to interpret this information.

The developer does provide citations from the literature indicating there are performance gaps for the

individual domains of care.

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

Yes/No: Yes

Justification and Notes: Although there are other measures in the HIQR program that address conceptually related domains of quality of care, such as the excess days in acute care after hospitalization measures for heart failure, acute myocardial infarction, and pneumonia that reflect care coordination, the vast majority of the structures hospitals would attest to implementing are not reflected in the existing measure set.

The developer has submitted MUC2022-032 Geriatrics Surgical Measure concurrently with this MUC, also for inclusion in the Hospital Inpatient Quality Reporting (IQR) Program. The attestation elements are similar across the two measures, although there are some variations and the Geriatrics Hospital Measure has more questions than the Geriatrics Surgical Measure. Implementing both measures applies the holistic framework to both older surgical patients and older patients who are admitted to the hospital or seen in the emergency department.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The developer notes that the measure includes some data elements that are in defined fields in electronic sources. The measure is submitted by attestation. This attestation would be done using a web-based tool within the HQR system. The developer indicates a workflow analysis was conducted; however, the results of that analysis are not presented, and it is reasonable to assume the data collection effort to reliably collect data on over 100 different hospital processes and structures is at least somewhat labor intensive.

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 for the hospital/facility/agency level of analysis and care setting. Reliability testing was provided by the developer noting a Test-Retest Kappa, Interrater Reliability (IRR) of 0.9, indicating a high degree of reliability of the measure result. The developer conducted a face validity assessment, although the developer did not provide specific results broken out by the group of experts or patients/caregivers that were voting on the validity of the measure result. The measure has not been submitted for NQF endorsement, nor has the measure been reviewed by the MAP in prior review cycles.

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 currently in use. The developer advanced a possible unintended consequence related to the encouragement of ambulation, which may inadvertently increase the rate of falls.

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PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed that while this is an important measure, rural providers do not have a large pool to hire clinicians which results in an ever-rotating staff of locums. Thus, rural health providers may be at a disadvantage in producing consistent documentation and reporting for measure compliance. The Rural Health Advisory Group expressed concern that there are limited social services resources in rural settings, thereby impacting one of the attestation questions included in the measure. The Rural Health Advisory Group expressed concern that public reporting of the measure could result in the erosion of community trust. Finally, the Rural Health Advisory Group noted that the measure is applicable across settings (i.e., includes the correct processes to take care of an older adult).

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed that geriatric patients are more fragile and emphasized the importance of assessing their needs. The Health Equity Advisory Group was not opposed to the concept of the measure but cited concerns regarding implementation and limited evidence that attestations lead to improved patient outcomes or further health equity.

Recommendation

Preliminary Analysis Recommendation:

Do Not Support for Rulemaking with the potential for mitigation.

The potential mitigation for this measure is a consideration for combining the two measures (MUC2022-112 and MUC2022-032) into a measure that is less burdensome and cross-walking the measures to be clear about where they align and where there are differences.

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

This measure under consideration (MUC) specifically addresses the Hospital Inpatient Quality Reporting Program (HIQR) high-priority areas of Care Coordination and Health Equity. The developer describes this measure as a programmatic measure that assesses provider infrastructure. The measure proposes a holistic approach to capture the care pathway for this unique population using provider attestation. The measure includes 14 attestation-based question across eight domains representing a comprehensive framework required for optimal care of older patients admitted to the hospital or being evaluated in the emergency department. A facility will receive a point for each domain where they attest to at least one corresponding statement (for a total of eight points).

MAP discussed the overlap between MUC2022-112 and MUC2022-032, and noted that hospitals, particularly ones in rural settings, may find it burdensome to report both measures. MAP members urged the developer to consider how to combine the two measures, or to focus on just one measure.

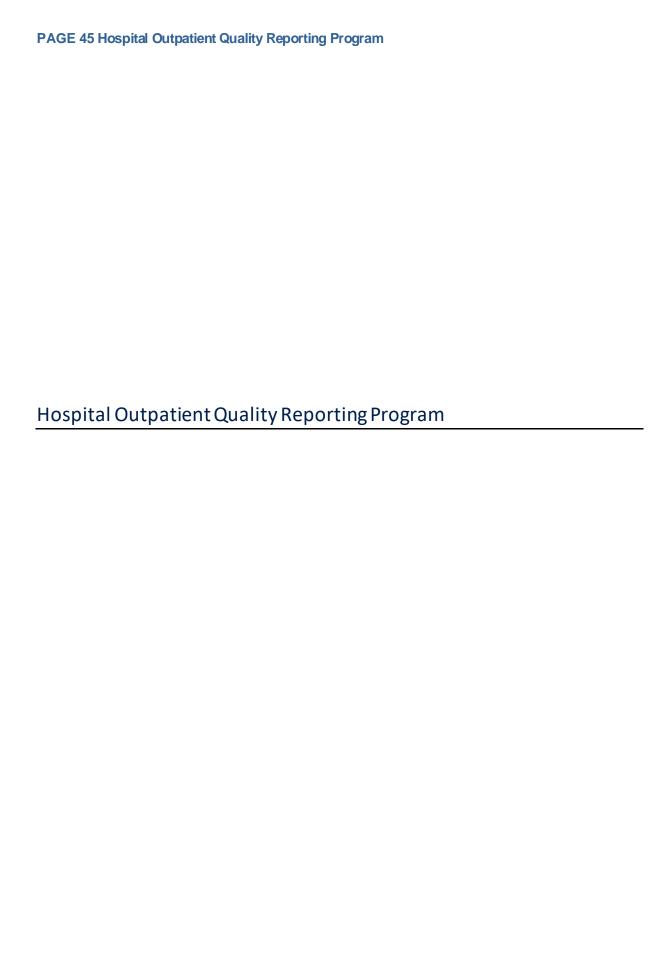
Summary: What is the potential impact of this measure on quality of care for patients?

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The patient population targeted by the optimal care framework advanced by this measure is older patients with complex care needs. According to the <u>US Administration on Aging (AoA)</u>, people age 65 years and older represent 16 percent of the population today, rising to nearly 22 percent by 2040. The report also underscores that nearly a quarter of these assessed their own health as fair or poor, with most older Americans having at least one chronic condition such as arthritis, heart disease, or cancer, and 40 percent having difficulty with mobility.

Across an unspecified number of sites, the average performance was hospitals attesting to having met 7 out of the 8 domains of optimal care for older patients. This does not indicate much room for improvement; however, the measure developer noted that sites participating in testing may not be representative of all hospitals.

The developer does provide citations from the literature indicating there are performance gaps for the individual domains of care. The developer also presented literature to support an association between the processes and structures assessed by this measure and clinical outcomes; however, it is not clear how this attestation based on this measure will directly lead to improved patient outcomes.



Preliminary Analysis – MUC2022-020 Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient)

Measure Description:

This electronic clinical quality measure (eCQM) provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses, a risk factor for cancer, while preserving image quality. It is expressed as a percentage of eligible CT exams that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam. All diagnostic CT exams of specified anatomic sites performed in hospital outpatient care settings (including emergency settings) are eligible.

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 addresses outcome eCQMs as a priority for the Hospital Outpatient Quality Reporting (OQR) program, and the Safety Meaningful Measures 2.0 Healthcare Priority. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which increases the risk of cancer.

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

Yes/No: Yes

Justification and Notes: This is an intermediate-outcome electronic clinical quality measure (eCQM) using electronic health data at the facility level that provides a standardized method for monitoring the performance of diagnostic computed tomography (CT) scan radiation doses, a risk factor for cancer, while preserving image quality. According to evidence provided in the developer's submission for consensus-based entity (CBE) endorsement in 2021, CT scans are used in most acute care facilities, and statistical inference suggests these scans cause approximately 2 percent of all new U.S. cancers diagnoses every year (Berrington de Gonzalez et al, 2009). The developer cites a retrospective cohort study finding a threefold increase in leukemia and brain cancer for pediatric patients who were CT scanned (Pierce et al., 2012).

The developer cites a randomized clinical trial of two interventions designed to reduce CT doses, finding "detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduced doses, particularly organ doses" (Smith-Bindman et al., 2020).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This measure addresses a patient safety concern of increased radiation dose from CT exams, as well as limited image quality of CT exams. The developer notes that doses used for CT vary substantially across imaging facilities for patients imaged for the same clinical indication. Specifically, the developer notes a study of 151 imaging facilities and hospitals where, after adjusting for

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patient characteristics, abdominal CT exams had a four-fold range in mean effective radiation dose and a 17-fold range in the proportion of high dose exams (<u>Smith-Bindman et al., 2019</u>). The developer does not argue that there is a persistent quality challenge in image quality for CT scans; rather, this component of the measure is included as a "balancing" element, to prevent an unintended consequence where an excessive reduction in CT doses might compromise image quality and the diagnostic process.

In testing at 16 hospital outpatient and emergency departments, the developer found mean performance at 31 percent, with a standard deviation of 8 percent, and minimum and maximum rates of 20 and 45 percent, respectively, indicating wide variation in performance and a substantial performance gap. For this measure, a lower score indicates better quality.

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

Yes/No: Yes

Justification and Notes: Though there are several other measures in the Hospital Outpatient Quality Reporting (OQR) program focused on patient safety, and others assessing efficiency in scanning processes or obtaining scanning results, none assess radiation dosage or other risks associated with cancer. The measure is being concurrently submitted for rulemaking in the Hospital Inpatient Quality Reporting (IQR) program, as well as the Merit-based Incentive Payment System (MIPS) program, encouraging alignment across these settings and across two otherwise separate levels of analysis. Reporting on this measure is applicable to a broad population: over a third of acute care hospitalizations involved at least one CT scan (Vance et al., 2013).

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure is an eCQM and according to the developer, all data elements are in defined fields in electronic sources. The developer conducted a feasibility assessment across seven different EHR systems at 15 different hospital sites, finding all data elements were available in structured fields, and no impact on clinician workflow. The National Quality Forum's Patient Safety Standing Committee rated the measure "High" for feasibility in its fall 2021 evaluation.

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 endorsed by a consensus-based entity (CBE) (NQF #3663e), is fully developed, and measure testing has demonstrated reliability and validity for the level of analysis. The measure was tested for reliability through a split-half correlation intraclass correlation coefficient (ICC), yielding a score of 0.99, indicating high reliability. NQF's Scientific Methods Panel and Patient Safety Standing Committee both rated the measure "High" for reliability in the fall 2021 evaluation. Likewise, both rated the measure "High" for validity in the same evaluation, based on a face validity assessment of a Technical Expert Panel (TEP) composed of both clinicians and patient advocates.

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?

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Yes/No: No

Justification and Notes: The developer identified a possible unintended consequence, suggesting that image quality of CT scans might deteriorate if the radiation dose was lowered. The developer notes that by specifying the measure to also capture CT exams reported as having low image quality, the incentives are aligned to produce CT scans that are within an appropriate range that balances safety considerations with image quality.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns regarding data collection.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The measure addresses safety and outcome eCQMs as priorities for the Hospital Outpatient Quality Reporting (OQR) program, and the "Safety" Meaningful Measures 2.0 Healthcare Priority. The focus of this measure is to reduce radiation doses from computerized tomography (CT) scans, which increases the risk of cancer. Although there are several other measures in the Hospital OQR program focused on patient safety, and others assessing efficiency in scanning processes or obtaining scanning results, none assess radiation dosage or other risks associated with cancer. The measure is being concurrently submitted for rulemaking in the Hospital Inpatient Quality Reporting (IQR) program, as well as the Merit-based Incentive Payment System (MIPS), encouraging alignment across these settings and across two otherwise separate levels of analysis. The measure is endorsed by a consensus-based entity (CBE) (National Quality Forum #3663e). Reporting on this measure is applicable to a broad population: over a third of acute care hospitalizations involved at least one CT scan (Vance et al., 2013).

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

This is an intermediate-outcome electronic clinical quality measure (eCQM) using electronic health data at the facility level that provides a standardized method for monitoring the performance of diagnostic

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computed tomography (CT) scan radiation doses, a risk factor for cancer, while preserving image quality. According to evidence provided in the developer's submission for consensus-based entity (CBE) endorsement in 2021, CT scans are used in most acute care facilities, and statistical inference suggests these scans cause approximately 2 percent of all new U.S. cancers diagnoses every year (Berrington de Gonzalez et al., 2009). The developer cites a retrospective cohort study finding a threefold increase in leukemia and brain cancer for pediatric patients who were CT scanned (Pierce et al., 2012).

The developer notes that doses used for CT vary substantially across imaging facilities for patients imaged for the same clinical indication. Specifically, the developer notes a study of 151 imaging facilities and hospitals where, after adjusting for patient characteristics, abdominal CT exams had a four-fold range in mean effective radiation dose and a 17-fold range in the proportion of high dose exams (Smith-Bindman et al., 2019). The developer cites a randomized clinical trial of two interventions designed to reduce CT doses, finding "detailed feedback on CT radiation dose combined with actionable suggestions and quality improvement education significantly reduced doses, particularly organ doses" (Smith-Bindman et al., 2020).

Preliminary Analysis – MUC2022-030 Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (formerly OP-26)

Measure Description:

Structural measure of facility capacity collects surgical procedure volume data on selected categories of outpatient procedures frequently performed within the outpatient department (e.g., outpatient surgery, cath lab, endoscopy). Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, Genitourinary, Cardiovascular, Respiratory, and Other

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 reports the volume of procedures performed at hospital outpatient departments (HOPDs) in select categories reflecting typical high-volume categories of procedures. Although the Hospital Outpatient Quality Reporting (OQR) Program currently contains some measures focused on cataract surgeries, colonoscopies, and chemotherapy, along with general urology and orthopedic measures, this measure under consideration (MUC) would capture the volume for many procedures previously not covered by the measure set. Measuring the volume of procedures relates to the program's goals of improving the safety and quality of outpatient procedures in HOPDs.

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

Yes/No: Yes

Justification and Notes: There is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review (<u>Levaillant et al., 2021</u>) found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies. A similar review, focused on outpatient surgeries, also found a volume-outcome relationship for across eight studies (<u>Stanak et al., 2020</u>).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This measure addresses a national trend where even complex surgeries are moving from inpatient to outpatient settings (MedPAC, 2021), and it leverages public reporting to help CMS and the public better understand possible quality differences between settings. This measure was previously in the Hospital OQR program, where it demonstrated a range in performance. Data from 2015 and 2016 demonstrates that the number of procedures performed by facilities in the 25th and 75th percentiles varied across the condition categories.

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

Yes/No: Yes

<u>Top of Document</u> | Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (formerly OP-26)

PAGE 51 Hospital Outpatient Quality Reporting Program

Justification and Notes: This measure was previously removed from the Hospital OQR program in CY2018 (see pp 59429 of the <u>Final Rule</u>), on the basis of the measurement burden outweighing the benefits to public reporting. However, electronic reporting of procedure volumes based on code lists should not be overly burdensome to hospitals, and the public reporting of specific procedure volumes may be useful to patients. In addition, MUC2022-028, ASC Facility Volume Data on Selected Surgical Procedures (formerly ASC-7), is submitted concurrently with this MUC, for inclusion in the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. The specifications are aligned to facilitate comparisons of equivalent procedure volumes across ambulatory surgery centers and hospital outpatient departments, the key goal of the programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the measure developer, all data elements for this measure are in defined fields in electronic sources. Hospitals can work from provided code sets to tabulate procedures performed in the prior calendar year using readily available electronic records; no abstraction is required. The measure was previously implemented in the program for six years, with facilities able to successfully report the measure.

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 developer has not submitted this measure for endorsement by a consensus-based entity (CBE); however, it is fully specified, and the care setting and level of analysis match the program requirements. Because this is a structural measure simply tabulating procedure counts, concerns with the reliability and validity of the measure result are minimized; nevertheless, the developer has not conducted reliability or validity testing. Reliability testing could be conducted on the data elements to ensure procedures are being tabulated appropriately, and validity testing could be conducted to compare results on this measure to other measures in the Hospital OQR program to establish whether the measure result is correlated with other quality measures.

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: This measure was previously removed from the Hospital OQR program in CY2018 (see pp 59429 of the <u>Final Rule</u>), on the basis of the measurement burden outweighing the benefits to public reporting. However, at the time some commenters noted that the measure presented substantial value for public reporting, and others noted that the administrative burden for facilities should be minimal. No specific implementation issues have been identified.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

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Yes/No: N/A

Hospice High Priority Areas

Yes/No: NA

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group discussed voluntary reporting of the measure for critical access hospitals (CAHs) due to low case volume and noted that more complex surgical procedures do not occur in these facilities. The Rural Health Advisory Group also noted that all data elements are in defined fields and electronic sources, thus requiring no manual abstraction.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concerns regarding the use of volume as a proxy for quality, and mentioned that public reporting of the measure may negatively impact health equity (i.e., healthier patients who are able may travel out of rural areas to seek care). Additionally, the Health Equity Advisory Group suggested that demographic data should be collected to understand whether there are differences in populations that access and receive services from ASCs versus HOPDs.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

This measure reports the volume of procedures performed at hospital outpatient departments (HOPDs) in select categories reflecting typical high-volume categories of procedures. Although the Hospital Outpatient Quality Reporting (OQR) Program currently contains some measures focused on cataract surgeries, colonoscopies, and chemotherapy, along with general urology and orthopedic measures, this measure under consideration (MUC) would capture the volume for many procedures previously not covered by the measure set. Measuring the volume of procedures relates to the program's goals of improving the safety and quality of outpatient procedures in HOPDs.

This measure was previously removed from the Hospital OQR program in CY2018 (see pp 59429 of the Final Rule), on the basis of the measurement burden outweighing the benefits to public reporting. However, electronic reporting of procedure volumes based on code lists should not be overly burdensome to hospitals, and the public reporting of specific procedure volumes may be useful to patients. In addition, MUC2022-028, ASC Facility Volume Data on Selected Surgical Procedures (formerly ASC-7), is submitted concurrently with this MUC, for inclusion in the Ambulatory Surgical Center Quality Reporting (ASCQR) Program. The specifications are aligned to facilitate comparisons of equivalent procedure volumes across ambulatory surgery centers and hospital outpatient departments, the key goal of the programs.

MAP raised a concern that rural and critical access hospitals, which provide outpatient care and report measures for the Hospital OQR program, may have low volume. MAP recommended that this concern be considered during the endorsement process.

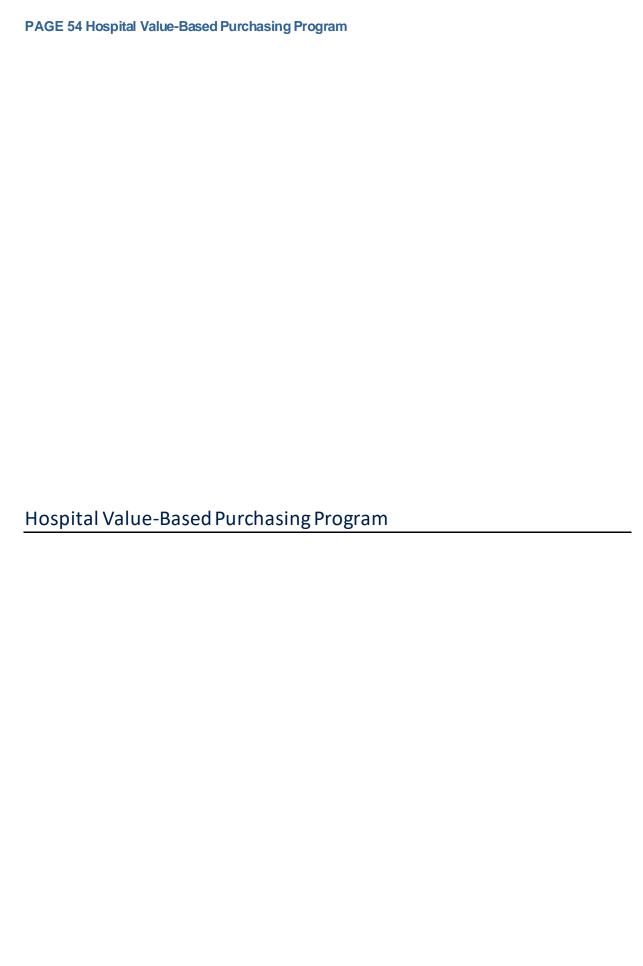
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Summary: What is the potential impact of this measure on quality of care for patients?

There is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review (<u>Levaillant et al., 2021</u>) found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies. A similar review, focused on outpatient surgeries, also found a volume-outcome relationship for across eight studies (<u>Stanak et al., 2020</u>).

This measure addresses a national trend where even complex surgeries are moving from inpatient to outpatient settings (MedPAC, 2021), and it leverages public reporting to help CMS and the public better understand possible quality differences between settings. This measure was previously in the Hospital OQR program, where it demonstrated a range in performance. Data from 2015 and 2016 demonstrates that the number of procedures performed by facilities in the 25th and 75th percentiles varied across the condition categories.



Preliminary Analysis – MUC2022-082 Severe Sepsis and Septic Shock: Management Bundle

Measure Description:

This measure focuses on adults 18 years and older with a diagnosis of severe sepsis or septic shock. Consistent with Surviving Sepsis Campaign guidelines, it assesses measurement of lactate, obtaining blood cultures, administering broad spectrum antibiotics, fluid resuscitation, vasopressor administration, reassessment of volume status and tissue perfusion, and repeat lactate measurement. As reflected in the data elements and their definitions, the first three interventions should occur within three hours of presentation of severe sepsis, while the remaining interventions are expected to occur within six hours of presentation of septic shock.

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 under consideration (MUC) specifically addresses the Meaningful Measures 2.0 Healthcare Priority of Safety. The literature suggests that bundles of care for severe sepsis and septic shock are associated with improved guideline compliance and lower hospital mortality (<u>Ferrer et al., 2008</u>) and (<u>Rhodes et al., 2015</u>). Additionally, absolute reductions in mortality of over 20 percent have been seen with measure compliance rates of 52 percent (<u>Levy et al., 2010</u>).

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

Yes/No: Yes

Justification and Notes: This composite MUC is associated with mortality prevention, as Centers for Medicare & Medicaid Services (CMS) representatives noted during the Measure Applications Partnership (MAP) 2021 Measure Set Review pilot review meeting that compliance with the measure produced a 5.7 percent mortality reduction for Medicare beneficiaries; per the 1.7 million sepsis cases a year, this result equals 15,000 lives saved. Studies have shown that the mortality difference is 14 percent among patients when all measure bundle elements are completed, compared to patients who do not have bundle completion (Coba et al., 2011). The literature suggests that, for patients with severe sepsis, standardized order sets, enhanced bedside monitor display, telemedicine, and comprehensive CQI feedback is feasible, modifies clinician behavior, and is associated with decreased hospital mortality (Thiel et al., 2009; Micek et al., 2006; Winterbottom et al., 2011; Schramm et al., 2011; Nguyen et al., 2007; Loyola et al., 2011).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: During the MAP 2021 Measure Set Review meeting, measure stewards noted that risk stratification for this measure has allowed for almost a 20 percent mortality reduction through early screening for sepsis. Propensity-matched 30-day adjusted mortality odds ratios for patients who were compliant versus not compliant with the measure showed a 0.77 mortality odds ratio (95 percent CI: 0.76–0.79, p-value < 0.001), indicating that cases that pass the measure have 0.77 times the odds of mortality of cases that fail the measure. Additionally, fifteen of the nineteen critical categorical dat a elements with a defined kappa had a kappa value in the moderate to high range (> 0.60). At the facility

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level, the risk ratio of 1.84 indicates that cases that fail the measure have 1.84 times the risk of dying compared to cases that pass the measure. Across all facilities, the mean and 25th percentile of reliability for each quarter exceeded the 0.70 threshold for acceptable reliability.

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 was reviewed in 2021 by MAP for the Measure Set Review pilot and was not recommended for removal. Adult Inpatient Risk Adjusted Sepsis Mortality (National Quality Forum (NQF) #3215) is a related measure that is used for public reporting and collects additional demographic variables (e.g., Source of Admission, Pregnancy Status), the actual lactate value and variables for severity adjustment and morbidity, which are used for risk adjustment. Both measures have similar populations but are different measure types; the measure under consideration assesses the performance rates of sepsis care processes and NQF 3215 evaluates the impact sepsis care processes have on an outcome, mortality rates.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the developer, all documentation required to report on the measure cannot currently be captured electronically in discrete fields, as the measure is complex and collecting the data necessary for reporting the measure requires data abstractors to review documentation in various formats including narrative free-text and identify the specific information necessary to report the measure. The developer also noted that there are no immediate plans to develop an electronic clinical quality measure (eCQM) because there is wide variation in the ability of hospitals to collect the necessary data for the measure in electronic fields. CMS representatives noted during the MAP 2021 Measure Set Review meeting that concerns have been raised with burden of data collection because this is a chart-based measure. The measure is already in operational use in the Hospital Inpatient Quality Reporting (IQR) 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: This measure is endorsed by the consensus-based entity (NQF #0500), fully developed and fully specified, and measure testing has demonstrated reliability and validity at the facility level of analysis. As of 2019, there were 3,084 hospitals with available measure data on the Timely and Effective Care hospital-level form on Care Compare. Data indicates improvement in the overall measure score over time from 50 percent in 2017 to 60 percent in 2019 for hospitals with available measure data nationwide.

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: During the MAP 2021 Measure Set Review meeting, CMS noted awareness of the concerns of overuse of the measure, and discussion has occurred regarding the creation of a

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balancing metric to evaluate this. Implementation challenges do not outweigh the benefits of the measure, as evidenced by public commenting and Coordinating Committee discussion during the MAP 2021 Measure Set Review meeting that highlighted the lives saved by the measure. The Infectious Diseases Society of America (IDSA) and other professional associations authored an editorial on the measure and called for its removal from the Hospital IQR program, stating that this measure would be the driver for the overuse of antibiotics, but an accompanying editorial criticized IDSA's response.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed the importance of the measure for rural health. However, the Rural Health Advisory Group raised the measure is time consuming to implement and may pose a challenge for rural providers due to staffing shortages.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional pending clarity being provided about the differences between the measure specifications reviewed by MAP and the current measure specifications.

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

This measure under consideration (MUC) specifically addresses the Meaningful Measures 2.0 Healthcare Priority of Safety. The literature suggests that bundles of care for severe sepsis and septic shock are associated with improved guideline compliance and lower hospital mortality (Ferrer et al., 2008, Rhodes et al., 2015). Additionally, absolute reductions in mortality of over 20 percent have been seen with measure compliance rates of 52 percent (Levy et al., 2010). The measure was reviewed in 2021 by the Measure Applications Partnership (MAP) for the Measure Set Review pilot and was not recommended for removal. Adult Inpatient Risk Adjusted Sepsis Mortality (National Quality Forum (NQF) #3215) is a related measure that is used for public reporting and collects additional demographic variables (e.g., Source of Admission, Pregnancy Status), the actual lactate value and variables for severity adjustment and morbidity, which are used for risk adjustment. Both measures have similar populations but are different measure types; the MUC assesses the performance rates of sepsis care processes and NQF #3215 evaluates the impact sepsis care processes have on outcome and mortality rates.

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MAP had a significant discussion around the version of the measure specifications reviewed by MAP, as the measure has been updated since the MUC submission and MAP was, therefore, reviewing an older version of the specification. The measure developer clarified that the measure is in use in the Hospital IQR program, and as a result, gets updated twice per year to clarify requirements and respond to feedback on the measure. The developer further clarified that the measure specifications reviewed by MAP reflect the latest clinical guidelines and align with the specifications submitted to the CBE for endorsement review, but do contain smaller updates related to the guidance for certain portions of the measure. MAP also noted the differences in opinion between those who support the measure and those who do not. Some MAP members were in strong support of the measure as it is closely linked to improved outcomes and demonstrates a performance gap. Others noted concern about the burden associated with chart abstraction and the need for hospitals to frequently update their data collection methods to align with the changing requirements of the measure. Some MAP members also expressed concern about the measure leading to a potential unintended consequence of antibiotic overuse.

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

This composite MUC is associated with mortality prevention, as Centers for Medicare & Medicaid Services (CMS) representatives noted during the MAP 2021 Measure Set Review meeting that compliance with the measure produced a 5.7 percent mortality reduction for Medicare beneficiaries; per the 1.7 million sepsis cases a year, this result equals 15,000 lives saved. Studies have shown that the mortality difference is 14 percent among patients when all measure bundle elements are completed, compared to patients who do not have bundle completion (Coba et al., 2011). The literature suggests that, for patients with severe sepsis, standardized order sets, enhanced bedside monitor display, telemedicine, and comprehensive CQI feedback is feasible, modifies clinician behavior, and is associated with decreased hospital mortality (Thiel et al., 2009; Micek et al., 2006; Winterbottom et al., 2011; Schramm et al., 2011; Nguyen et al., 2007; Loyola et al., 2011). During the MAP 2021 Measure Set Review meeting, measure stewards noted that risk stratification for this measure has allowed for almost a 20 percent mortality reduction through early screening for sepsis. Propensity-matched 30-day adjusted mortality odds ratios for patients who were compliant versus not compliant with the measure showed a 0.77 mortality odds ratio (95 percent CI: 0.76–0.79, p-value < 0.001), indicating that cases that pass the measure have 0.77 times the odds of mortality of cases that fail the measure. Additionally, fifteen of the nineteen critical categorical data elements with a defined kappa had a kappa value in the moderate to high range (> 0.60). At the facility level, the risk ratio of 1.84, indicates that cases that fail the measure have 1.84 times the risk of dying compared to cases that pass the measure. Across all facilities, the mean and 25th percentile of reliability for each quarter exceeded the 0.70 thresholds for acceptable reliability.



Preliminary Analysis – MUC2022-078 Psychiatric Inpatient Experience Measurement

Measure Description:

The measure is a 23-item five-point Likert scale (i.e., "strongly agree, agree, neutral, disagree, strongly disagree" as well as a "does not apply" option) survey to assess the experience of patients who have received inpatient psychiatric services. The survey measures four key domains of patient experience for inpatient psychiatric care settings, including Relationship with the Treatment Team, Nursing Presence, Treatment Effectiveness, and the Healing Environment.

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 a Centers for Medicare & Medicaid Services (CMS) high priority for future measure consideration as a patient-reported outcome performance measure (PRO-PM) focusing on the patient experience of care in an Inpatient Psychiatric Facility. There are currently no PRO-PMs in the Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP). It is similar to the Hospital-Consumer Assessment of Healthcare Providers & System (HCAHPS) measures, but the existing HCAHPS measures specifically exclude behavioral health from their protocol and are not validated for the inpatient psychiatric care setting.

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

Yes/No: Yes

Justification and Notes: This is a patient-reported outcome performance measure (PRO-PM). The developer states that the evidence for this measure is based on a systematic review that identifies the methodological quality of the psychometric properties of instruments measuring quality and satisfaction with care from the perspective of mental health patients and professionals and found five such instruments that stand out as yielding good to excellent values in quality criteria (<u>Sanches-Balcells et al, 2018</u>).

The measure developer then conducted their own study to develop a psychometrically valid survey using rigorous measurement development and validation processes. The resulting Yale Psychiatric Inpatient Experience survey integrates patient experience theory as well as aspects of patient-centered care that are important to psychiatric inpatients (<u>Klemanski et al, 2022</u>).

According to information from the developer, patient experience improvement is an under-researched area within psychiatry and behavioral health, therefore the evidence base is rather limited. However, there is evidence that facilities can have an impact on the overall experience through the core domains measured in the PIX survey. For example, in a randomized controlled trial, staff received training on evidence-based methods of group intervention and milieu management, resulting in an improved experience of the healing environment (a core domain of the PIX survey). In addition, the developer notes that the therapeutic alliance (relationship with the treatment team) is protective against rehospitalization and self-harm events, and the relationship with the inpatient treatment team is also related to positive health outcomes. There is evidence that interventions can result in an improved therapeutic relationship, and help manage patients' symptoms while in the hospital.

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Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer states that data show a performance gap. This is demonstrated by comparing scores to the national average HCAHPS top box scores. Among the nationally reported HCAHPS questions, the average top box scores range from 54 percent to 80 percent, with an overall average of 70 percent. The current measure's top box results are similar to those from the HCAHPS, ranging from 55 percent to 72 percent, with an overall average of 64 percent, at the facility level. This range of performance suggests 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: There are currently no PRO-PMs in the Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP). This measure is similar to the HCAHPS measures, but the existing HCAHPS measures specifically exclude behavioral health from their protocol and are not validated for the inpatient psychiatric care setting.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: No data are in defined fields in electronic sources. The developer states that data transfers would occur via third-party vendors in the same way HCAHPS surveys are currently transferred.

Data feasibility was evaluated via field testing using both paper-based and electronic surveys that were offered and collected prior to patient discharge from an inpatient facility. In-person survey collection sites received survey responses from approximately 50 percent of total discharges over a two-year period.

An additional pilot was performed using email and paper-based surveys that were distributed post-discharge. The post-discharge email and paper-based surveys returned < 3 percent of the total surveys distributed.

The developer considered the collection burden on providers and found that provider workflows did have to be modified to accommodate this measure.

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 in in pilot (beta) testing and has not yet been submitted for endorsement by a consensus-based entity (CBE). Testing occurred in inpatient psychiatric facilities and matches both the intended population (inpatient psychiatric patients) and level of analysis (facility). The developer used a split-half correlation analysis and found that split-half reliability was 0.93 (n=1,648). The developer conducted face validity testing among a 25-person panel of experts and patients/caregivers but does not provide the results. The developer also conducted a confirmatory factor analysis to test how well the measured variables fit the construct, with a comparative fit index

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(CFI) of 0.92. This analysis examines the difference between the data and the hypothesized model. CFI values range from 0 to 1, with larger values indicating a better fit.

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 yet in current use but the developer notes that implementation of a survey tool that is collected prior to patient discharge may have several potential unintended consequences:

- 1) There may be a small cost associated with technology or human capital resources;
- 2) There may be less focus on improving care processes that are not measured by the survey;
- 3) Pre-discharge surveys are potentially gamed or falsified;
- 4) Survey results may be subject to misinterpretation due to measurement error or bias.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed support for psychiatric inpatient experience data collection. Patient support of the measure was especially strong. However, the Rural Health Advisory Group raised concerns regarding costs related to implementation and maintenance. The Rural Health Advisory Group also expressed reservations regarding selection bias or submission bias if patient surveying occurs prior to discharge. The Rural Health Advisory Group noted that there are few inpatient psychiatric hospitals in rural communities and discussed the applicability of the measure.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group shared that this measure is a step in the right direction for behavioral health. The Health Equity Advisory Group expressed concerns that the denominator may not represent the population. One Advisory Group member expressed that "treatment effectiveness" lacks specificity.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement of the measure by a consensus-based entity (CBE), broader testing in a variety of settings, an analysis of the timing of survey administration (pre-

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versus post-discharge), an analysis of other factors that may drive differences in performance (e.g., involuntary commitments, patient factors), and a consideration of how the proportion of involuntary versus voluntary admissions affects the measured outcome.

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

This measure addresses a Centers for Medicare & Medicaid Services (CMS) high priority for future measures considered as a patient-reported outcome performance measure (PRO-PM) focusing on the patient experience of care in an Inpatient Psychiatric Facility. There are currently no PRO-PMs in the Inpatient Psychiatric Facility Quality Reporting Program (IPF QRP). It is similar to the Hospital-Consumer Assessment of Healthcare Providers & System (HCAHPS) measures, but the existing HCAHPS measures specifically exclude behavioral health from their protocol and are not validated for the inpatient psychiatric care setting.

MAP supported the measure concept but recommended further testing of the measure, particularly around the timing of survey administration (pre- versus post-discharge), the mode of administration (e.g., via email, mail), and the type of provider (e.g., rural, safety net), and how these different scenarios and settings impact measure performance. MAP also noted that facilities will have different numbers of involuntary commitments and recommended that the measure developer explore how the proportion of involuntary admissions impacts a facility's measure performance.

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

The developer demonstrates a performance gap by comparing the measure's scores to the national average HCAHPS top box scores. Among the nationally reported HCAHPS questions, the average top box scores range from 54 percent to 80 percent, with an overall average of 70 percent. The current measure's top box results are similar to those from the HCAHPS, ranging from 55 percent to 72 percent, with an overall average of 64 percent, at the facility level.

PAGE 64 Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program
Prospective Payment System-Exempt Cancer Hospital Quality
Reporting Program

Preliminary Analysis – MUC2022-120 Documentation of Goals of Care Discussions Among Cancer Patients

Measure Description:

This measure assesses goals of care discussion documentation among patients with cancer who die while receiving care at the reporting hospital. In this process measure, reported annually, hospitals will report the percent of cancer patients who died during the reporting period and had the patient's goals of care documented prior to death.

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 under consideration (MUC) specifically addresses the Meaningful Measures 2.0 Healthcare Priority of Person-centered Care, and the Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQRP) high priority area of care coordination. The literature suggests that physician-patient communication is essential to patient coping, shared decision making, and patient quality of life, especially as patients near the end of their lives (<u>Bernacki et al., 2014</u>).

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

Yes/No: Yes

Justification and Notes: Studies indicate a gap between cancer patient and family goals and the care they receive (Wright et al., 2016; Wright et al., 2010). Additionally, goals of care discussions with patients with advanced cancers commence too late, about one month before death (Yung et al., 2010). Goals of care discussions are associated with better patient and family outcomes and less intensive care toward the end of life (Cheung et al., 2015; Temel et al., 2010; Zhang et al., 2009; Wright et al., 2008).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Measuring documentation of goals of care discussions is an important step toward achieving the outcome of goal concordant care. Documentation of goals in structured fields prompts discussions, enhances their quality and efficiency, and promotes accessibility. Across 10 cancer centers, the mean for data reported from Q4 2021 for all decedents is 36 percent (standard deviation (SD) 25), and for inpatient decedents is 40 percent (SD 25), while the mean for data reported from Q1 2022 for all decedents is 29 percent (SD 30) and for inpatient decedents is 39 percent (SD 30).

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

Yes/No: Yes

Justification and Notes: NQF 1641: Hospice and Palliative Care – Treatment Preferences is a similar measure that is used for public reporting and assesses documentation of life-sustaining treatment preferences among seriously ill patients enrolled in hospice care receiving specialty palliative care in an

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acute hospital setting. Both measures are process measures in the inpatient/hospital setting that document discussions between physician and patient, but the MUC is specific to cancer patients. As the measure is fully applicable to hospitals, the measure result is useful to a broad population.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure was alpha tested in April 2022. The developer provided eight hospitals with the measure specifications and performed a feasibility analysis. The developer shared findings of this alpha testing with their technical expert panel. The developer found two primary challenges at this phase of developed identified: (1) for the denominator, reliably identifying patients who died external to the reporting hospital; and (2) for the numerator, the participating hospitals are at different stages of provider use of structured documentation to capture patient goals and ability to ability to generate reports of the presence of documentation in the "patient goals" field of the medical record (i.e., to completely remove the need for manual medical record abstraction. The developer expects these challenges to be resolved through continued maturation of the electronic health records and education.

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 new measure has not been submitted for endorsement by a consensus-based entity, nor is it fully developed or fully specified. Measure testing is currently underway.

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 current use, so no negative unintended issues to the patient or implementation challenges have been identified.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed strong patient support for this measure. The Rural Health Advisory Group highlighted that access to the information provided by the measure is important as care may be provided in the primary care setting. The Rural Health Advisory Group also shared that the creation of templates within the EHR can make information accessible and structured.

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MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no health equity concerns. The Health Equity Advisory Group noted that this measure may not have broad generalized applicability with only eight PPS-exempt cancer hospitals.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure reliable and valid, and endorsement by a consensus-based entity (CBE).

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

This measure under consideration (MUC) specifically addresses the Meaningful Measures 2.0 Healthcare Priority of Person-centered Care, and the Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (PCHQRP) high-priority area of care coordination. The literature suggests that physician-patient communication is essential to patient coping, shared decision-making, and patient quality of life, especially as patients near the end of their lives (Bernacki et al., 2014). NQF 1641: Hospice and Palliative Care – Treatment Preferences is a similar measure that is used for public reporting and assesses documentation of life-sustaining treatment preferences among seriously ill patients enrolled in hospice care receiving specialty palliative care in an acute hospital setting. Both measures are process measures in the inpatient/hospital setting that document discussions between physician and patient, but the MUC is specific to cancer patients. As the measure is fully applicable to hospitals, the measure result is useful to a broad population.

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

Studies indicate a gap between cancer patient and family goals and the care they receive (Wright et al., 2016; Wright et al., 2010). Additionally, goals of care discussions with patients with advanced cancers commence too late, about one month before death (Yung et al., 2010). Goals of care discussions are associated with better patient and family outcomes and less intensive care toward the end of life (Cheung et al., 2015; Temel et al., 2010; Zhang et al., 2009; Wright et al., 2008). Measuring documentation of goals of care discussions is an important step toward achieving the outcome of goal concordant care. Documentation of goals in structured fields prompts discussions, enhances their quality and efficiency, and promotes accessibility. Across 10 cancer centers, the mean for data reported from Q4 2021 for all decedents is 36 percent (standard deviation (SD) 25), and for inpatient decedents is 40 percent (SD 25), while the mean for data reported from Q1 2022 for all decedents is 29 percent (SD 30) and for inpatient decedents is 39 percent (SD 30).

PAGE 68 Rural Emergency Hospital Quality Reporting Program (REHQRP)
Rural Emergency Hospital Quality Reporting Program (REHQRP)
Ratar Emergency mospital quanty reporting mogram (RETQRI)

Preliminary Analysis – MUC2022-039 Median Time from emergency department (ED) Arrival to ED Departure for Discharged ED Patients

Measure Description:

Median time from ED arrival to time of departure from the ED for patients discharged from the ED. The measure is calculated using chart abstracted data, on a rolling quarterly basis, and is publicly reported in aggregate for one calendar year. The measure has been publicly reported since 2013 as part of the ED Throughput measure set of the CMS Hospital Outpatient Quality Reporting (OQR) Program.

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 under consideration (MUC) addresses the critical quality objective of efficiency for the Rural Emergency Hospital Quality Reporting Program (REHQRP). This measure is recommended by the CMS Center for Clinical Standards and Quality (CCSQ) leadership for adoption in the REHQRP.

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

Yes/No: No

Justification and Notes: This measure was reviewed by the National Quality Forum (NQF) Cost and Efficiency Standing Committee in the spring of 2018 and lost endorsement as it did not meet the importance to measure and report criterion. There is a lack of evidence that a change in wait times influences mortality or other patient outcomes. The developer's literature review, which was also submitted for endorsement review, notes the importance of this measure primarily in the realm of patient satisfaction. There is a relationship between emergency departments (EDs) with shorter wait times and higher ED volume, as well as a decrease in the number of patients who left without being seen.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: During the consensus-based entity (CBE) endorsement review of this measure, the Standing Committee acknowledged an overall change from 2014-2016 of approximately four minutes but questioned whether this was meaningful change in performance. The Standing Committee also raised concern of whether the performance gap in this measure is true variation in hospital quality, or rather a function of provider characteristics. Differences in performance have also been found to vary based on location, facility size, and type (i.e., teaching versus non-teaching facilities). The endorsement review noted that ED throughput time could not be interpreted without an understanding of the mix of acuity at a given ED. For use in the REHQRP, these concerns may be more acute as rural emergency departments will be disproportionally smaller with lower volume, thus it is not clear this measure will be a true indicator of quality.

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

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Yes/No: No

Justification and Notes: While the measure was initially endorsed for 10 years, prior to losing endorsement in the spring of 2018, there was limited improvement in throughput time during the 10-year endorsement period. The Standing Committee expressed concern regarding the validity of the measure particularly related to the need for risk adjustment. The Committee noted it is not clear how meaningful the measure results are without information on the case mix or diagnostic information. Without this information, the Committee said it is difficult to interpret variation in median ED wait time and may not adequately account for differences in patient type and facilities.

This measure was also reviewed in the 2022 Measure Applications Partnership (MAP) Measure Set Review (MSR) with a vote of "conditional support for removal" from the Hospital Outpatient Quality Reporting (OQR) Program. CMS noted during MAP's review that the measure was not submitted for reendorsement because it requires specification and algorithm changes related to abstraction of the data elements. MAP voted "conditional support for removal" because the measure lost CBE endorsement, and the measure has been in the Hospital OQR program for some time with limited change in the rates that are publicly reported. Of note, during the 2022 MAP MSR Rural Health Advisory Group meeting, a member noted rural hospitals could potentially perform well on this measure, and so, its removal from the Hospital OQR program would take away one of those opportunities for higher performance; nevertheless, they still expressed support for removing the measure from that program measure set.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The developer notes that the required data elements are routinely generated/collected during provision of care and data is abstracted from a record by another individual than the individual who obtained the original information. According to the developer, all data elements are in defined fields in electronic sources. The developer gathered feedback on this measure from a nine-expert work group via an online survey. The majority of the respondents agreed or strongly agreed that this measure does not cause undue burden on hospital for its data. Respondents also noted that the data elements are currently available in a structured field in the electronic health record.

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 developed, specifications are provided and the measure is specified for the facility level of analysis. However, the measure under consideration (MUC) lost CBE endorsement (NQF #0496) based on concerns regarding the validity of the measure specifications, and the evidence to support the measure specifications.

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 has been in use in the Hospital HOQR program. It is not clear if the performance gap in the measure is true variation in hospital quality, or related to the mix of acuity at a given ED. Furthermore, MAP voted "conditional support for removal" of this measure for the Hospital

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OQR program during the 2022 Measure Set Review.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns regarding the impact of weather and local facility transport modalities on transfer times, and noted that some remote facilities may hold a patient for longer due to weather and transport safety issues. The Rural Health Advisory Group expressed that transfer time for trauma patients is especially important. Stakeholders raised concerns that issues related to distance and time can be outside the control of the facility.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group emphasized the importance of the measure and highlighted the opportunity to advance health equity.

Recommendation

Preliminary Analysis Recommendation:

Do Not Support for Rulemaking

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

While the measure addresses an important measurement domain of hospital efficiency, the measure under consideration (MUC) is no longer endorsed by the consensus-based entity (National Quality Forum (NQF) #0496) due to concerns that median wait times may not be a true indicator of provider quality and may be more related to the facility size and the acuity of patients seen. For use in the Rural Emergency Hospital Quality Reporting Program (REHQRP), these concerns may be more acute as rural emergency departments will be disproportionally smaller with lower volume, thus it is not clear this measure will be a true indicator of quality.

MAP agreed that publicly reporting ED wait times could have potential negative unintended consequences, as patients may avoid EDs with longer wait times, even when patients need urgent care. A MAP member asked whether data collected as part of the Medicare Beneficiary Quality Improvement Project (MBQIP) could provide insight into how rural hospitals may perform on the measure.

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

There is limited impact of this measure as there is a lack of evidence that a change in wait times influences mortality or other patient outcomes. While the developer provided evidence of a performance gap, it is not clear if this performance gap is true variation in hospital quality. The

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consensus-based entity (CBE) endorsement review noted that emergency department (ED) throughput time could not be interpreted without an understanding of the mix of acuity at a given ED. This measure was also reviewed in the 2022 Measure Applications Partnership (MAP) Measure Set Review (MSR) with a vote of "conditional support for removal" from the Hospital Outpatient Quality Reporting (OQR) Program. MAP voted "conditional support for removal" because the measure lost CBE endorsement, and it has been in the Hospital OQR program for some time but there has been limited change in the rates that are publicly reported. Of note, during the 2022 MAP MSR Rural Health Advisory Group meeting, a member noted rural hospitals could potentially perform well on this measure, and so, its removal from the Hospital OQR program would take away one of those opportunities for higher performance; nevertheless, they still expressed support for removing the measure from that program measure set.

Preliminary Analysis – MUC2022-066 Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy

Measure Description:

Facility-level risk-standardized rate of acute, unplanned hospital visits within 7 days of a colonoscopy procedure performed at a Rural Emergency Hospital among Medicare Fee-For-Service (FFS) patients aged 65 years and older. An unplanned hospital visit is defined as an emergency department (ED) visit, observation stay, or unplanned inpatient admission.

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: Inclusion of this measure in the Rural Emergency Hospital Quality Reporting Program (REHQRP) will allow the Centers for Medicare & Medicaid Services (CMS) to report quality information on colonoscopies performed in facilities that acquire the newly established REH designation. The measure supports the goal of the program to promote equity in health care for those living in rural communities by improving patient outcomes.

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

Yes/No: Yes

Justification and Notes: Colonoscopy is a common and costly procedure performed at outpatient facilities and is frequently used among relatively healthy patients to screen for colorectal cancer. Given the widespread use of colonoscopy, understanding and minimizing procedure-related adverse events is a high priority. These adverse events, such as abdominal pain, bleeding, and intestinal perforation, can result in unanticipated hospital visits. Most (68 percent) emergency department (ED) visits following outpatient colonoscopy are due to the colonoscopy (Grossberg et al., 2018). The developer provides a logic model as part of their submission for endorsement by a consensus-based entity (CBE) that outlines provider-level and facility-level interventions that can be undertaken to reduce the risk of unplanned hospital visits. These provider-level factors include protocols for patient's colonoscopy prep and technical quality of the procedure. The facility-level factors include anesthesia, discharge, and follow-up protocols.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: A version of this measure (CMIT ID 02086) is currently in use in the Ambulatory Surgical Center Quality Reporting (ASCQR) and Hospital Outpatient Quality Reporting (OQR) programs. The developer cites performance data for all hospital outpatient departments (HOPDs) captured by the current colonoscopy measure, which includes but is not limited to entities that will convert to REHs. Between January 1, 2016 and December 31, 2018, there were 2,258,661 colonoscopies performed in non-federal acute care HOPDs and 2,524,898 performed in ambulatory surgical centers (ASCs). The risk-standardized hospital visit rates (RSHVRs) per 1,000 colonoscopies ranged from 11.67 to 24.27 (median: 16.38). This distribution of measure scores suggests substantial variation in performance among HOPDs, which likely may indicate that entities that will confirm to REHs will have a similar range in performance.

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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: A previous version of this measure specified for colonoscopies performed in ASCs and HOPDs received CBE endorsement in 2014 and 2020 (National Quality Forum (NQF) #2539). That measure (CMITID 02086) is currently in use in the ASCQR and Hospital OQR programs. This measure captures data for colonoscopies performed at facilities that acquire the newly established REH designation, which includes but is not limited to entities captured by the previous measure. The newly established REH program does not yet address unplanned hospital visits within seven days of a colonoscopy procedure performed at REHs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure uses Medicare beneficiary enrollment and claims data that are already defined in electronic sources. Administrative claims data used in this measure are routinely captured as part of the billing process and no fees are associated with data collection.

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: This measure is specified for use in the REH setting. A previous version of this measure specified for colonoscopies performed in ASCs and HOPDs received CBE endorsement in 2014 and 2020 (NQF #2539). That measure (CMIT ID 02086) is currently in use in the ASCQR and Hospital OQR programs. It was tested using data from ASCs and HOPDs. Some HOPDs that currently capture data for this measure will convert to REHs.

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 currently in use in the ASCQR and Hospital OQR programs. No unintended consequences to the patient were identified during measure development, testing, or implementation.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

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The Rural Health Advisory Group noted that the measure is currently in the Hospital OQR Program. The Rural Health Advisory Group supported the measure and expressed no rural health concerns.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group shared that the measure appears to advance health equity. The Health Equity Advisory Group expressed concerns regarding patient selection (i.e., bias toward less risky patients) and the impact on health equity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The goal of this risk-standardized, outcome-based measure is to improve patient outcomes by providing patients, physicians, hospitals, and policy makers with information about facility-level 7-day, risk-standardized hospital visit rates (RSHVRs) following outpatient colonoscopy at rural emergency hospitals (REHs). The measure targets high variability in hospital performance and aligns with the Rural Emergency Hospital Quality Reporting Program (REHQRP) goal to promote equity in health care for those living in rural communities by improving patient outcomes. The newly established REHQRP does not yet address unplanned hospital visits within seven days of a colonoscopy procedure performed at REHs.

A previous version of this measure specified for colonoscopies performed in ambulatory surgical centers (ASCs) and hospital outpatient departments (HOPDs) received endorsement from the consensus-based entity (CBE) in 2014 and 2020 (National Quality Forum (NQF) #2539). That measure (CMITID 02086) is currently in use in the Ambulatory Surgical Center Quality Reporting (ASCQR) and Hospital Outpatient Quality Reporting (OQR) programs.

MAP questioned whether rural emergency hospitals would have enough cases to report the measure and some members questioned whether MUC2022-066 and MUC2022-067 could be combined. CMS responded that this would require development of a new measure. Other MAP members observed that colonoscopies may be more common in rural emergency hospitals than other types of procedures or surgeries and supported the importance of this measure for patients in rural settings.

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

Nearly 70 percent of emergency department (ED) visits following outpatient colonoscopy are due to the colonoscopy (Grossberg et al., 2018). The developer cites performance data for all hospital outpatient departments (HOPDs) captured by the current colonoscopy measure, which includes but is not limited to entities that will convert to REHs. Between January 1, 2016 and December 31, 2018, there were 2,258,661 colonoscopies performed in non-federal acute care HOPDs and 2,524,898 performed in ambulatory surgical centers (ASCs). The risk-standardized hospital visit rates (RSHVRs) per 1,000 colonoscopies ranged from 11.67 to 24.27 (median: 16.38). This distribution of measure scores suggests substantial variation in performance among HOPDs, which likely may indicate that entities that will confirm to REHs will have a similar range in performance.

Preliminary Analysis – MUC2022-067 Risk-standardized hospital visits within 7 days after hospital outpatient surgery

Measure Description:

Facility-level risk-standardized rate of acute, unplanned hospital visits within 7 days of an outpatient surgical procedure performed at a Rural Emergency Hospital among Medicare Fee-For-Service (FFS) patients aged 65 years and older. An unplanned hospital visit is defined as an emergency department (ED) visit, observation stay, or unplanned inpatient admission.

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: Inclusion of this measure in the Rural Emergency Hospital Quality Reporting Program (REHQRP) will allow the Centers for Medicare & Medicaid Services (CMS) to report information on risk-standardized rates of acute, unplanned hospital visits within seven days of an outpatient surgical procedure performed in facilities that acquire the newly established REH designation. The measure supports the goal of the program to promote equity in health care for those living in rural communities by improving patient outcomes.

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

Yes/No: Yes

Justification and Notes: Hospital utilization following same-day surgery is an important and accepted patient-centered outcome reported in the literature. Nearly 70 percent of all surgeries in the U.S. are now performed in the outpatient setting with most performed as same-day surgeries at hospital outpatient departments (HOPDs) (Cullen et al., 2009). While most outpatient surgery is safe, there are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unanticipated hospital visits. The developer provides a list of strategies and interventions to reduce unplanned hospital visits following outpatient surgery, including appropriate patient selection; patient education; appropriate management of post-operative nausea, vomiting, and pain; and improving technical quality, including procedural technique and anesthesia.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Hospital visit rates vary among HOPDs (<u>Bain et al., 1999</u>), suggesting variation in surgical and discharge care quality; this includes but is not limited to facilities that will convert to REHs. According to the developer's summary of the evidence, estimates of hospital visit rates within the first 30 days following surgery vary from less than one percent to 28 percent depending on the type of surgery, the outcome measured (inpatient admissions alone or with ED visits, and observation stays), outcome timeframe (e.g., 7, 14, or 30 days), and patient characteristics (e.g., age, sex). Up to 40 percent of direct admissions after outpatient surgery have been found to be preventable (<u>Awan et al., 2013</u>). The developer also provided data demonstrating a quality gap for HOPDs, as HOPDs may opt to become REHs. Of the 3,974 facilities (representing data from January 1, 2018-December 31, 2018), the range of RSHVRs was 0.54-2.39 (IQR 0.93-1.07), indicating a quality gap.

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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: A previous version of the measure specified for surgeries performed in the HOPD setting received consensus-based entity (CBE) endorsement in 2015 and 2020 (National Quality Forum (NQF) #2687). That measure (CMITID 02930) is currently in use in the Hospital Outpatient Quality Reporting (OQR) program. This measure captures data for surgeries performed at facilities that acquire the newly established REH designation, which includes but is not limited to entities captured by the previous measure. The newly established REH program does not yet address unplanned hospital visits within seven days of an outpatient surgical procedure.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: This measure uses Medicare beneficiary enrollment and claims data that are already defined in electronic sources. Administrative claims data used in this measure are routinely captured as part of the billing process and no fees are associated with data collection.

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: This measure is specified for use in the REH setting. A previous version of the measure specified for surgeries performed in the HOPD setting received CBE endorsement in 2015 and 2020 (NQF #2687). That measure (CMIT ID 02930) is currently in use in the Hospital OQR program. Some HOPDs that currently capture data for that measure will convert to REHs.

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 currently in use in the Hospital OQR program. During the public comment period when the measure was first proposed in the 2017 Hospital Outpatient Prospective Payment System (OPPS) rule, there was concern that providers may avoid certain patients and procedures, depending on the inclusion criteria and robustness of the risk adjustment. However, the measure was adopted and no unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

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MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group noted that the measure is currently in the Hospital OQR Program. The Rural Health Advisory Group supported the measure and expressed no rural health concerns.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group shared that the measure appears to advance health equity. The Health Equity Advisory Group expressed concerns regarding patient selection (i.e., bias toward less risky patients) and the impact on health equity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The goal of this fully developed, outcome-based measure is to reduce adverse patient outcomes associated with preparation for same-day surgery, the surgery itself, and follow-up care, by capturing and making more visible to providers and patients unplanned hospital visits following outpatient surgery at rural emergency hospitals (REHs). The measure targets high variability in hospital performance and aligns with the goal of the Rural Emergency Hospital Quality Reporting Program (REHQRP) to promote equity in health care for those living in rural communities by improving patient outcomes. The newly established REHQRP does not yet address unplanned hospital visits within seven days of an outpatient surgical procedure performed at REHs.

A previous version of the measure specified for surgeries performed in the hospital outpatient department (HOPD) setting received consensus-based entity (CBE) endorsement in 2015 and 2020 (National Quality Forum (NQF) #2687). That measure (CMITID 02930) is currently in use in the Hospital Outpatient Quality Reporting (OQR) program.

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

Nearly 70 percent of surgeries in the U.S. are performed in outpatient settings (<u>Cullen et al., 2009</u>). Hospital admissions are costly for payers and burdensome to patients, and there is a broad effort across programs to reduce excess admissions. Up to 40 percent of direct admissions after outpatient surgery are preventable (<u>Awan et al., 2013</u>). According to the developer's summary of the evidence, estimates of hospital visit rates within the first 30 days following surgery vary from less than one percent to 28 percent depending on the type of surgery, the outcome measured (inpatient admissions alone or with ED visits, and observation stays), outcome timeframe (e.g., 7, 14, or 30 days), and patient characteristics (e.g., age, sex). The developer also provided data demonstrating a quality gap for HOPDs, as HOPDs may opt to become REHs. Of the 3,974 facilities (representing data from January 1, 2018-December 31, 2018), the range of RSHVRs was 0.54-2.39 (IQR 0.93-1.07), indicating a quality gap.

Preliminary Analysis – MUC2022-081 Abdomen Computed Tomography (CT) Use of Contrast Material

Measure Description:

This measure calculates the percentage of abdomen studies that are performed with and without contrast out of all abdomen studies performed (those with contrast, those without contrast, and those with both).

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 addresses a critical priority of patient safety in rural hospitals for the Rural Emergency Hospital Quality Reporting Program (REHQRP). Specifically, given that a computed tomography (CT) abdomen is a common imaging procedure in the Medicare population, this measure helps to ensure that CT abdomen imaging is aligned with current clinical guidance at rural emergency hospitals, while avoiding the potentially harmful effects of unnecessary radiation and contrast exposure.

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

Yes/No: Yes

Justification and Notes: The developer provides an evidence attachment noting that the American College of Radiology (ACR) published three new and three updated Appropriateness Criteria in 2020 and 2021 related to the use of CT abdomen studies without and/or with contrast material. Across the appropriateness criteria, the ACR states that studies with **and** without contrast are usually not appropriate (with one exception).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: In initial public reporting of this measure in 2011 for the Hospital Outpatient Quality Reporting (OQR) program, the median performance on the measure was 9.5 percent in 2011 and dropped to 1.4 percent in 2021. This suggests that the quality performance of abdomen CT studies improved nationally with public reporting. In public reporting year 2020, rural, small (0-50 beds), and government-owned facilities accounted for a disproportionally high percentage of outlier facilities (45.1 percent, 37.6 percent, and 0.9 percent, respectively), indicating an opportunity for performance improvement for rural hospitals. It is important to note that the measure has not been tested for rural emergency hospitals and thus the performance gap is not known specifically but a related analysis by the developer suggests an improvement opportunity.

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 REHQRP does not have a CT imaging quality measure. The measure has been in use in the Hospital OQR program since 2011 and therefore will promote alignment between

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rural emergency hospitals and hospital outpatient departments.

The Measure Applications Partnership (MAP) Coordinating Committee reviewed this measure as part of the 2022 Measure Set Review. MAP conditionally supported retaining the measure in the Hospital OQR program with a condition of endorsement by a consensus-based entity (CBE). MAP acknowledged the initial CBE endorsement attempt was in 2008 and there have been changes to the measure since that date. MAP noted removing the measure may create a gap in the program.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The data elements for this measure are in defined fields in electronic sources. The developer also notes that the measure is calculated using data from final claims that facilities submit for Medicare beneficiaries enrolled in fee for service Medicare. The measure has been in the Hospital OQR program since 2011.

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: A previous version of this measure was endorsed by the consensus-based entity (National Quality Forum (NQF) #0513) but the developer did not seek re-endorsement, thus the measure is no longer endorsed. The measure is fully developed and tested in the hospital outpatient department setting. The measure is proposed to be used in the REHQRP, however, there is no reliability and validity testing of the updated submitted 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: No

Justification and Notes: This measure is currently used in the Hospital OQR program and is being submitted as-is for the REHQRP. The measure has been in use from 2011 to present.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group discussed the measure in detail and cited no concerns with regard to rural health.

MAP Health Equity Advisory Group Input:

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The Health Equity Advisory Group expressed the importance of the measure and the opportunity to advance health equity.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement of the measure by a consensus-based entity (CBE).

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

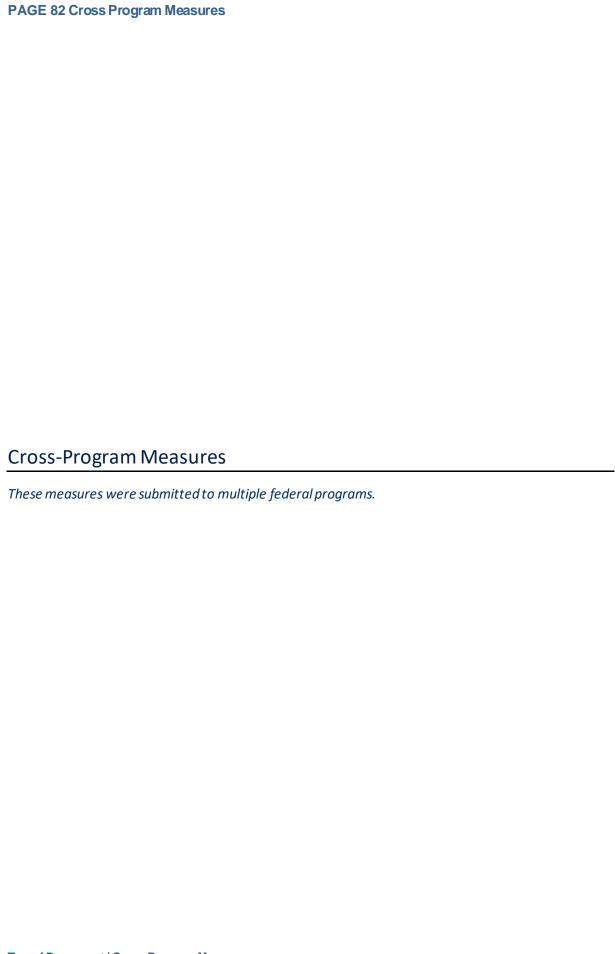
The measure addresses a critical priority of patient safety in rural hospitals for the Rural Emergency Hospital Quality Reporting Program (REHQRP). Specifically, given that a computed tomography (CT) abdomen is a common imaging procedure in the Medicare population, this measure helps to ensure that CT abdomen imaging is aligned with current clinical guidance at rural emergency hospitals, while avoiding the potentially harmful effects of unnecessary radiation and contrast exposure.

The Measure Applications Partnership (MAP) Coordinating Committee reviewed this measure as part of the 2022 Measure Set Review. MAP conditionally supported retaining the measure in the Hospital OQR program with a condition of endorsement by a consensus-based entity (CBE). During the Measure Set Review, MAP acknowledged the initial CBE endorsement attempt was in 2008 and there have been changes to the measure since that date. MAP noted removing the measure may create a gap in the program.

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

The developer provides an evidence attachment noting that the American College of Radiology (ACR) published three new and three updated Appropriateness Criteria in 2020 and 2021 related to the use of CT abdomen studies without and/or with contrast material. Across the appropriateness criteria, the ACR states that studies with and without contrast are usually not appropriate (with one exception). Given that a CT abdomen is a common imaging procedure in the Medicare population, this measure helps to ensure that CT abdomen imaging is aligned with current clinical guidance, while avoiding the potentially harmful effects of unnecessary radiation and contrast exposure.

The measure has been used in the Hospital Outpatient Quality Reporting (OQR) program since 2011. Performance data from that program reveals that rural, small (0-50 beds), and government-owned facilities account for a disproportionally high percentage of outlier facilities (45.1 percent, 37.6 percent, and 0.9 percent, respectively), indicating an opportunity for performance improvement for rural hospitals.



Preliminary Analysis – MUC2022-024 Hospital Harm - Acute Kidney Injury (Hospital IQR)

Program: Hospital Inpatient Quality Reporting Program

Measure Description:

The proportion of inpatient hospitalizations for patients 18 years of age or older who have an acute kidney injury (stage 2 or greater) that occurred during the encounter as evidenced by a substantial increase in serum creatinine value, or by the initiation of kidney dialysis (continuous renal replacement therapy [CRRT], hemodialysis or peritoneal dialysis).

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: As an outcome-focused, electronic clinical quality measure (eCQM) which addresses a potential patient safety issue in acute care facilities, this measure addresses two high priority areas (safety, outcome eCQMs) for future measure consideration for the Hospital Inpatient Quality Reporting (IQR) program. This measure also relates to the goals for a focus on high-impact and outcome-based measures within CMS' Meaningful Measures Framework.

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-focused eCQM. The developer notes important clinical interventions that can be undertaken to influence this outcome. According to the measure developer, while acute kidney injury (AKI) may be due to natural progression of underlying illness or a complication of a necessary treatment such as chemotherapy, a proportion of AKI cases are preventable and treatable. The 2012 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines suggest careful management for the prevention of AKI. Both worsening renal function and injury requiring dialysis have lasting negative impact including loss of kidney function, uremic complications, and symptoms associated with drug toxicity and volume overload (Hoste & De Corte., 2011; Levey & James., 2017; Liborio et. al., 2015). Literature also suggests that there are early AKI treatment interventions which can prevent AKI, such as nephrotoxic avoidance, drug dose adjustment, and attention to fluid balance (Perazella, 2012; Onuigbo et al., 2017).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This safety eCQM captures the number of patients who had AKI, as evidenced by a substantial increase in serum creatinine, or the initiation of renal dialysis (hemodialysis or peritoneal dialysis) during the hospitalization. According to the measure developer, published literature suggests that the incidence of AKI in general hospitalized patients is 10-20 percent, in intensive care unit (ICU) patients it ranges from 10-20 percent, and in cardiac surgery patients it ranges from 30-50 percent (Thongprayoon, 2020).

Using electronic health record (EHR) data from 20 hospitals for year 2020, the measure developer found

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that hospital-level measure performance rates ranged from 0.76 percent (for every 1,000 qualified hospital admissions there were 7.6 inpatient encounters where patients suffered AKI) to 4.43 percent (for every 1,000 qualified hospital admissions there were 44 inpatient encounters where patients suffered AKI), with a system-wide, weighted average rate equal to 1.52 percent. This data suggests AKI rates can be improved in some hospital systems.

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 is currently one existing measure in the Centers for Medicare & Medicaid Services (CMS) Measure Inventory Tool (CMIT) that is similar to this measure. AKI is encompassed in the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Indicator (PSI) 90 composite, under the provider-level PSI 10: Postoperative Acute Kidney Injury Requiring Dialysis Rate (CMIT Ref No. 05021) measure. However, the measure developer points out a few notable differences between the PSI 10 measure and the measure under consideration. PSI 10 assesses how often hospitalized patients had renal failure requiring dialysis after having an operation. Additionally, PSI 10 utilizes claims data and is not endorsed by a consensus-based entity (although the composite PSI 90 (CMIT Ref No.03282/05537), of which it is a component, is endorsed). In comparison, the measure under consideration assesses how often AKI occurs in the inpatient hospital setting and is an eCQM. The measure developer also notes that there is currently no measure in a CMS quality reporting program or public reporting that quantifies how often AKI occurs in hospitalized patients.

This eCQM was also submitted to the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals program during this pre-rulemaking cycle.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The developer tested the measure for feasibility by surveying 34 hospital inpatient acute care facilities (17 using Meditech EHRs and 17 using Cerner EHRs). According to the measure developer, all data elements for this measure are in defined fields in electronic sources. The measure uses currently available and propagated EHR data to identify the proportion of stage 2 or greater KDIGO stage of AKI. The measure developer provided an analysis of the feasibility of the critical data elements used in the measure as well as a provider workflow analysis. The developer reported feasibility challenges with two data elements; however, they also reported the sites were able to ultimately report these data elements by retrieving the data in different ways.

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: This measure has been submitted for endorsement to the National Quality Forum (NQF) but has not yet been reviewed (NQF #3713e); however, it is fully developed and specified. The developer tested the measure in a sample of 20 hospitals (17 hospitals using Meditech and three using Cerner).

The developer conducted reliability testing using a signal-to-noise ratio and random split-half correlation. The signal-to-noise ratio produced a result of 0.91, indicating the measure has strong

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measure score-level reliability. The intra-class correlation coefficient (ICC), using the split-half sample approach and a sample size of 20, produced a result of 0.79, also indicating strong measure score-level reliability.

The developer conducted validity using the following test paired with their results: percent agreement (0.95), Kappa (0.92), Positive Predictive Value or PPV (0.91), and Sensitivity (0.79). The Kappa result indicates strong concordance and inter-rater agreement between data exported from the EHR and data in the patients' chart. The PPV result demonstrate a high probability of correctly classifying an AKI event among patients that truly experienced an AKI event. The lower Sensitivity result may be due to a technology glitch. Overall, the results indicate a strong measure score-level validity.

The developer also conducted empiric validity testing using known groups validity, comparing teaching hospitals with non-teaching hospitals. With a sample size of 20, the known groups validity resulted in 0.73. The result indicates that teaching hospitals performed (27 percent) better than non-teaching hospitals, urban hospitals performed (22 percent) better than rural hospitals, and large-sized hospitals performed better than small-sized hospitals. Lastly, the developer conducted face validity with a sample of 11 voting experts, with 11 in agreement about the face validity of 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: No

Justification and Notes: The measure developer did not identify any unintended consequences during eCQM development or testing. However, the developer noted that 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.

The measure developer notes it is possible that by measuring AKI in the hospital setting, some hospital clinicians may be less likely to provide aminoglycoside antibiotics, nonsteroidal anti-inflammatory drugs (NSAIDs), or other medications that are thought to contribute to the occurrence of AKI in some patients. Increased incentives to avoid these medications could lead to higher pain burden in some patients, although alternative medications are always available.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns regarding data collection and staffing shortages which may result in higher rates of acute kidney injury in rural communities.

MAP Health Equity Advisory Group Input:

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The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement of the measure by a consensus-based entity (CBE).

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

The purpose of this outcome-focused, electronic clinical quality measure (eCQM) is to understand the proportional instance of acute kidney injuries (AKIs) in hospital inpatient facilities. This measure aligns with CMS's goals for high-impact and outcome-based measures, and aligns with two high priority areas (safety, outcome eCQMs) for the Hospital Inpatient Quality Reporting (IQR) Program. Additionally, this measure fills a gap in measurement and provides incentives for hospital quality improvement, as there is no current inpatient AKI measure in the Hospital Inpatient Quality Reporting Program.

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

This safety eCQM captures the number of patients who had acute kidney injury (AKI), as evidenced by a substantial increase in serum creatinine, or the initiation of renal dialysis (hemodialysis or peritoneal dialysis) during the hospitalization. According to the measure developer, published literature suggests that the incidence of AKI in general hospitalized patients is 10-20 percent, in intensive care unit (ICU) patients it ranges from 10-20 percent, and in cardiac surgery patients it ranges from 30-50 percent (Thongprayoon, 2020). Literature also suggests that there are early AKI treatment interventions which can prevent AKI, such as nephrotoxic avoidance, drug dose adjustment, and attention to fluid balance (Perazella, 2012; Onuigbo et al., 2017). As noted by the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, AKIs impose a heavy burden of illness (morbidity and mortality) and managing AKIs have a high cost per person. Systematically measuring the rates of AKI in the hospital setting will provide hospitals with a reliable and timely assessment and will allow for hospitals to improve quality and reduce AKI harm rates.

Preliminary Analysis – MUC2022-024 Hospital Harm - Acute Kidney Injury (Medicare Promoting Interoperability Program)

Program: Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs)

Measure Description:

The proportion of inpatient hospitalizations for patients 18 years of age or older who have an acute kidney injury (stage 2 or greater) that occurred during the encounter as evidenced by a substantial increase in serum creatinine value, or by the initiation of kidney dialysis (continuous renal replacement therapy [CRRT], hemodialysis or peritoneal dialysis).

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: As an outcome-focused, electronic clinical quality measure (eCQM) which addresses a potential patient safety issue in acute care facilities, this measure relates to the goals for a focus on high-impact and outcome-based measures within CMS' Meaningful Measures Framework. The measure also aligns with CMS' goals to improve interoperability as part of the National Quality Strategy.

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-focused eCQM. The developer notes important clinical interventions that can be undertaken to influence this outcome. According to the measure developer, while AKI may be due to natural progression of underlying illness or a complication of a necessary treatment such as chemotherapy, a proportion of AKI cases are preventable and treatable. The 2012 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines suggest careful management for the prevention of AKI. Both worsening renal function and injury requiring dialysis have lasting negative impact including loss of kidney function, uremic complications, and symptoms associated with drug toxicity and volume overload (Hoste & De Corte., 2011; Levey & James., 2017; Liborio et. al., 2015). Literature also suggests that there are early AKI treatment interventions which can prevent AKI, such as nephrotoxic avoidance, drug dose adjustment, and attention to fluid balance (Perazella, 2012; Onuigbo et al., 2017).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: This safety eCQM captures the number of patients who had AKI, as evidenced by a substantial increase in serum creatinine, or the initiation of renal dialysis (hemodialysis or peritoneal dialysis) during the hospitalization. According to the measure developer, published literature suggests that the incidence of AKI in general hospitalized patients is 10-20 percent, in intensive care unit (ICU) patients it ranges from 10-20 percent, and in cardiac surgery patients it ranges from 30-50 percent (Thongprayoon, 2020).

Using electronic health record (EHR) data from 20 hospitals for year 2020, the measure developer found

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that hospital-level measure performance rates ranged from 0.76 percent (for every 1,000 qualified hospital admissions there were 7.6 inpatient encounters where patients suffered AKI) to 4.43 percent (for every 1,000 qualified hospital admissions there were 44 inpatient encounters where patients suffered AKI), with a system-wide, weighted average rate equal to 1.52 percent. This data suggests AKI rates can be improved in some hospital systems.

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 is currently one existing measure in the Centers for Medicare & Medicaid Services (CMS) Measure Inventory Tool (CMIT) that is similar to this measure. AKI is encompassed in the Agency for Healthcare Research and Quality's (AHRQ) Patient Safety Indicator (PSI) 90 composite, under the provider-level PSI 10: Postoperative Acute Kidney Injury Requiring Dialysis Rate (CMIT Ref No. 05021) measure. However, the measure developer points out a few notable differences between the PSI 10 measure and the measure under consideration. PSI 10 assesses how often hospitalized patients had renal failure requiring dialysis after having an operation. Additionally, PSI 10 utilizes claims data and is not endorsed by a consensus-based entity (although the composite PSI 90 (CMIT Ref No.03282/05537), of which it is a component, is endorsed). In comparison, the measure under consideration assesses how often AKI occurs in the inpatient hospital setting and is an eCQM. The measure developer also notes that there is currently no measure in a CMS quality reporting or public reporting program that quantifies how often AKI occurs in hospitalized patients.

This eCQM was also submitted to the Hospital Inpatient Quality Reporting Program (IQR) during this prerulemaking cycle.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The developer tested the measure for feasibility by surveying 34 hospital inpatient acute care facilities (17 using Meditech EHRs and 17 using Cerner EHRs). According to the measure developer, all data elements for this measure are in defined fields in electronic sources. The measure uses currently available and propagated EHR data to identify the proportion of stage 2 or greater KDIGO stage of AKI. The measure developer provided an analysis of the feasibility of the critical data elements used in the measure as well as a provider workflow analysis. The developer reported feasibility challenges with two data elements; however, they also reported the sites were able to ultimately report these data elements by retrieving the data in different ways.

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: This measure has been submitted for endorsement to the National Quality Forum (NQF) but has not yet been reviewed (NQF #3713e); however, it is fully developed and specified. The developer tested the measure in a sample of 20 hospitals (17 using Meditech and three using Cerner).

The developer conducted reliability testing using a signal-to-noise ratio and random split-half correlation. The signal-to-noise ratio, using a sample size of 20, produced a result of 0.91, indicating the

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measure has strong measure score-level reliability. The intra-class correlation coefficient (ICC), using the split-half sample approach and a sample size of 20, produced a result of 0.79, also indicating strong measure score-level reliability.

The developer conducted validity using the following test paired with their results: percent agreement (0.95), Kappa (0.92), Positive Predictive Value or PPV (0.91), and Sensitivity (0.79). The Kappa result indicates strong concordance and inter-rater agreement between data exported from the EHR and data in the patients' chart. The PPV result demonstrate a high probability of correctly classifying an AKI event among patients that truly experienced an AKI event. The lower Sensitivity result may be due to a technology glitch.

The developer also conducted empiric validity testing using known groups validity, comparing teaching hospitals with non-teaching hospitals. With a sample size of 20, the known groups validity resulted in 0.73. The result indicates that teaching hospitals performed (27 percent) better than non-teaching hospitals, urban hospitals performed (22 percent) better than rural hospitals, and large-sized hospitals performed better than small-sized hospitals. Lastly, the developer conducted face validity with a sample of 11 voting experts, with 11 in agreement about the face validity of 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: No

Justification and Notes: The measure developer did not identify any unintended consequences during eCQM development or testing. However, the developer noted that 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.

The measure developer notes it is possible that by measuring AKI in the hospital setting, some hospital clinicians may be less likely to provide aminoglycoside antibiotics, nonsteroidal anti-inflammatory drugs (NSAIDs), or other medications that are thought to contribute to the occurrence of AKI in some patients. Increased incentives to avoid these medications could lead to higher pain burden in some patients, although alternative medications are always available.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Impact Act Domain

Yes/No:

Justification:

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

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The Rural Health Advisory Group expressed concerns regarding data collection and staffing shortages which may result in higher rates of acute kidney injury in rural communities.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement of the measure by a consensus-based entity (CBE).

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

The purpose of this outcome-focused, electronic clinical quality measure (eCQM) is to understand the proportional instance of acute kidney injuries (AKIs) in hospital inpatient facilities. As the measure developer demonstrated across 20 hospitals, the reliable use of EHR data elements contributes to the interoperability of this measure and aligns with CMS's goal to embed quality in the care journey. Additionally, this eCQM fills a gap in measurement, as there is no current inpatient AKI measure in a CMS program.

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

This safety eCQM captures the number of patients who had acute kidney injury (AKI), as evidenced by a substantial increase in serum creatinine, or the initiation of renal dialysis (hemodialysis or peritoneal dialysis) during the hospitalization. According to the measure developer, published literature suggests that the incidence of AKI in general hospitalized patients is 10-20 percent, in intensive care unit (ICU) patients it ranges from 10-20 percent, and in cardiac surgery patients ranges from 30-50 percent (Thongprayoon, 2020). Literature also suggests that there are early AKI treatment interventions which can prevent AKI, such as nephrotoxic avoidance, drug dose adjustment, and attention to fluid balance (Perazella, 2012; Onuigbo et al., 2017). As noted by the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) guidelines, AKIs impose a heavy burden of illness (morbidity and mortality) and managing AKIs have a high cost per person. Systematically measuring the rates of AKI in the hospital setting will provide hospitals with a reliable and timely assessment and will allow for hospitals to improve quality and reduce AKI harm rates.

Preliminary Analysis – MUC2022-026 Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the HOPD or ASC Setting (ASCQR)

Program: Ambulatory Surgical Center Quality Reporting Program

Measure Description:

The measure will estimate a facility-level risk-standardized improvement rate for patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare fee-for-service (FFS) patients 65 years of age or older. Substantial clinical benefit (SCB) improvement will be measured by the change in score on the joint-specific patient-reported outcome measure (PROM) instruments, measuring hip or knee pain and functioning, from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 275 to 425 days following surgery).

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 fully-developed measure addresses the high priority areas of patient and family engagement in their care and communication/care coordination for the Ambulatory Surgical Center Quality Reporting (ASCQR) program. The measure supports the goals of the Meaningful Measures 2.0 framework to prioritize patient-reported outcome measures (PROMs) and align measures across federal value-based programs. The program currently does not include a measure that assesses patient-reported outcomes (PROs) among total hip or knee arthroplasty (THA/TKA) patients at the ambulatory surgical center (ASC) level.

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

Yes/No: Yes

Justification and Notes: Addressing quality of care for common and costly procedures such as THAs and TKAs is essential. THAs and TKAs are common surgeries among Medicare beneficiaries, with Medicare direct payments to hospitals for THA/TKA exceeding \$15 billion annually (Miller et al., 2011). According to the developer methodology report from March 2022, between April 1, 2017 to October 2, 2019, there were 786,830 THA and TKA procedures performed in the inpatient setting for Medicare fee-for-service (FFS) beneficiaries 65 years and older. Some project that annual THA and TKA procedures performed in the U.S. will reach nearly 2 million by 2030 (Lopez et al., 2020). The developer cites several studies indicating how providers can improve outcomes of THA/TKA patients by addressing aspects of pre-, peri, and postoperative care. Further, the developer cites studies that suggest that optimal clinical outcomes may be influenced by the surgeon performing the procedure, the team's efforts in the care of the patient, care coordination across provider groups and specialties, and the patients' engagement in their own recovery (Feng et al., 2018; Saufl et al., 2007).

Does the measure address a quality challenge?

Yes/No: Yes

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Justification and Notes: The goal of this measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. THA and TKA procedures are commonly performed in older patients who have noticeable pain and functional limitation preoperatively, and who often experience substantial improvement in quality of life postoperatively due to decreasing pain and improving function (Wiklund & Romanus, 1991; Laupacis et al., 1993; Rissanen et al., 1995; Ritter et al., 1995). While the measure is tested and endorsed at the hospital level, only preliminary results are available for hospital outpatient departments (HOPDs). The measure has not been tested in the ASC setting. Among inpatient hospitals, the mean distribution of hospitals' risk-standardized improvement rates (RSIRs) is 6.65 to 86.84 (median: 66.5 percent; interquartile range: 54.36 to 72.51 percent). This variation in hospital performance is indicative of an important quality gap that may apply to ASCs as well.

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 Applications Partnership (MAP) supported a prior version of this measure for rulemaking in the Hospital Inpatient Quality Reporting (IQR) program during the 2020-2021 pre-rulemaking cycle. That measure, Centers for Medicare & Medicaid Services' (CMS) Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMITID 03198), has been adopted for use in the Hospital IQR program. While the hospital-level measure was ultimately supported by MAP, MAP members raised several validity concerns for the consensus-based entity (CBE) endorsement committee to consider. These concerns included the attribution of changes in joint function to hospitals versus rehabilitation services during the follow-up interval, the exclusion of staged procedures potentially eliminating up to 43 percent of procedures, and the clinical basis of the 25-case volume exclusion threshold.

This measure, MUC2022-026, is under consideration for use in ASCs for the ASCQR program and in HOPDs for the Hospital Outpatient Quality Reporting (OQR) program. The key strategy for the ASCQR program is to ensure that procedures done in any type of facility have equivalent quality. As such, measures of quality of procedures in hospital settings should extend to ASCs, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types.

Recently, CMS removed the procedures from the inpatient-only (IPO) list and now allows elective primary THA/TKA procedures to be performed in both the HOPD and ASC settings. Since the onset of the COVID-19 pandemic in 2020, outpatient THA/TKA procedures outnumber inpatient procedures. Given the proportion of THA/TKA procedures that are moving to the outpatient setting, this measure fills a gap by measuring performance at the HOPD/ASC facility level.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure uses Medicare administrative claims data and the Hospital Quality Reporting (HQR) tool. While comprehensive data are unavailable for the ASC and HOPD settings, the measure developer performed a feasibility assessment using PRO data collected from the Center for Medicare and Medicaid Innovation (CMMI) Comprehensive Care for Joint Replacement (CJR) model. Some hospitals that report data for CJR inadvertently submit data on procedures performed in HOPDs,

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therefore demonstrating the feasibility of implementing this measure in the Hospital OQR program. The same data fields would also be collected from ASC facilities.

The 2020-2021 pre-rulemaking cycle considered a hospital-level version of this measure (National Quality Forum (NQF) #3559). When considering the hospital-level version of this measure, MAP members expressed concern regarding data collection and reporting. The developer mentioned that they have worked to mitigate burden by reducing the number of questions to a very small number. That measure was endorsed (NQF #3559) and received a moderate rating for feasibility, suggesting that this ASC-version is feasible as well.

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 at the facility-level of analysis and was tested in the hospital inpatient acute care facility and HOPD settings. Because the measure is only endorsed at the hospital-level (NQF #3559) and only preliminary data are available for the HOPD setting, comprehensive reliability, validity, and risk-adjustment testing data are unavailable for the ASC and HOPD settings. However, the developer states that it is highly likely that the facility-level reliability of the measure for procedures performed at ASCs and HOPDs will be similar to the inpatient hospital measure due to the same minimum volume threshold (>=25 cases). While both the hospital-level version of the measure and the measure under consideration (MUC) are specified for the same population (Medicare fee-for-service patients 65 years of age and older undergoing elective THA/TKA procedures), the specifications of post-operative data collection vary slightly. The hospital-level measure collects post-operative data 300 to 425 days following surgery, whereas the MUC is specified to collect post-operative data 275 to 425 days following surgery.

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: CMS adopted the hospital-level version of the measure for use in the Hospital IQR program. Prior to mandatory reporting, CMS will conduct two voluntary reporting periods in 2025 and 2026. No unintended consequences to the patient were identified during measure development or testing.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

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The Rural Health Advisory Group discussed challenges with implementing the PROM instrument and noted the decreased availability of post-operative healthcare services (i.e., physical therapy) in rural settings. Consequently, the Rural Health Advisory Group questioned whether telehealth services could be included in the measure.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concerns regarding patient selection (i.e., bias toward less risky patients) and the impact on health equity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The goal of this patient-reported, outcome-based performance measure (PRO-PM) is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. The measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of patient and family engagement and communication/care coordination for the Ambulatory Surgical Center Quality Reporting (ASCQR) program. Currently, the program does not include a measure that assesses patient-reported outcomes (PROs) among total hip or knee arthroplasty (THA/TKA) patients at the ambulatory surgical center (ASC) level.

A version of this measure, Centers for Medicare & Medicaid Services' (CMS) Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMITID 03198), has been adopted for use in the Hospital Inpatient Quality Reporting (IQR) program. This measure, MUC2022-026, is under consideration for use in ASCs for the ASCQR program and in hospital outpatient departments (HOPDs) for the Hospital Outpatient Quality Reporting (OQR) program. The key strategy for the ASCQR program is to ensure that procedures done in any type of facility have equivalent quality. As such, measures of quality of procedures in hospital settings should extend to ASCs, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types.

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

THAs and TKAs are common surgeries among Medicare beneficiaries. Estimates suggest that annual THA and TKA procedures performed in the U.S. will reach nearly 2 million by 2030. PROs among THA/TKA patients vary across hospitals. Among inpatient hospitals, the mean distribution of hospitals' risk-standardized improvement rates (RSIRs) ranged from 6.65 to 86.84 percent (median: 66.5 percent; interquartile range: 54.36 to 72.51 percent). This variation across hospitals, which may also apply to ASCs, suggests opportunities for improvement in quality of care. The measure seeks to improve patient outcomes following elective primary THA/TKA by providing information to patients, physicians, and facilities about facility-level, risk-standardized PROs, such as pain and functional status. This measure is risk-adjusted for patients' comorbid conditions and the goal of the measure is to provide facilities with performance information to implement focused quality improvement efforts.

Preliminary Analysis – MUC2022-026 Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA PRO-PM) in the HOPD or ASC Setting (Hospital OQR)

Program: Hospital Outpatient Quality Reporting Program

Measure Description:

The measure will estimate a facility-level risk-standardized improvement rate for patient-reported outcomes (PROs) following elective primary THA/TKA for Medicare fee-for-service (FFS) patients 65 years of age or older. Substantial clinical benefit (SCB) improvement will be measured by the change in score on the joint-specific patient-reported outcome measure (PROM) instruments, measuring hip or knee pain and functioning, from the preoperative assessment (data collected 90 to 0 days before surgery) to the postoperative assessment (data collected 275 to 425 days following surgery).

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 fully-developed measure addresses the high priority areas of personcentered care and patient-reported outcome performance measures (PRO-PMs) for the Hospital Outpatient Quality Reporting (OQR) program. The measure supports the goals of the Meaningful Measures 2.0 framework to prioritize patient-reported outcome measures (PROMs) and align measures across federal value-based programs. The program currently does not include a measure that assesses patient-reported outcomes (PROs) among total hip or knee arthroplasty (THA/TKA) patients at the hospital outpatient department (HOPD) level.

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

Yes/No: Yes

Justification and Notes: Addressing quality of care for common and costly procedures such as THAs and TKAs is essential. THAs and TKAs are common surgeries among Medicare beneficiaries, with Medicare direct payments to hospitals for THA/TKA exceeding \$15 billion annually (Miller et al., 2011). According to the developer methodology report from March 2022, between April 1, 2017 to October 2, 2019, there were 786,830 THA and TKA procedures performed in the inpatient setting for Medicare fee-for-service (FFS) beneficiaries 65 years and older. Some project that annual THA and TKA procedures performed in the U.S. will reach nearly 2 million by 2030 (Lopez et al., 2020). The developer cites several studies indicating how providers can improve outcomes of THA/TKA patients by addressing aspects of pre-, peri, and postoperative care. Further, the developer cites studies that suggest that optimal clinical outcomes may be influenced by the surgeon performing the procedure, the team's efforts in the care of the patient, care coordination across provider groups and specialties, and the patients' engagement in their own recovery (Feng et al., 2018; Saufl et al., 2007).

Does the measure address a quality challenge?

Yes/No: Yes

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Justification and Notes: The goal of this measure is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. THA and TKA procedures are commonly performed in older patients who have noticeable pain and functional limitation preoperatively, and who often experience substantial improvement in quality of life postoperatively due to decreasing pain and improving function (Wiklund & Romanus, 1991; Laupacis et al., 1993; Rissanen et al., 1995; Ritter et al., 1995). While the measure is tested and endorsed at the hospital level, only preliminary results are available for HOPDs. The measure has not been tested in the ambulatory surgical center (ASC) setting. Among inpatient hospitals, the mean distribution of hospitals' risk-standardized improvement rates (RSIRs) is 6.65 to 86.84 percent (median: 66.5 percent; interquartile range: 54.36 to 72.51 percent). This variation in hospital performance is indicative of an important quality gap that may apply to HOPDs, as well.

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 Applications Partnership (MAP) supported a prior version of this measure for rulemaking in the Hospital Inpatient Quality Reporting (IQR) program during the 2020-2021 pre-rulemaking cycle. That measure, Centers for Medicare & Medicaid Services' (CMS) Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMIT ID 03198), has been adopted for use in the Hospital IQR program. While the hospital-level measure was ultimately supported by MAP, MAP members raised several validity concerns for the consensus-based entity (CBE) endorsement committee to consider. These concerns included the attribution of changes in joint function to hospitals versus rehabilitation services during the follow-up interval, the exclusion of staged procedures potentially eliminating up to 43 percent of procedures, and the clinical basis of the 25-case volume exclusion threshold.

This measure, MUC2022-026, is under consideration for use in ASCs for the Ambulatory Surgical Center Quality Reporting (ASCQR) program and in HOPDs for the Hospital OQR program. As care moves more toward the ambulatory side, it is important to ensure that procedures and clinical care in hospital settings are of equal high quality and that consumers can compare care across facilities, including HOPDs.

Recently, CMS removed the procedures from the inpatient-only (IPO) list and now allows elective primary THA/TKA procedures to be performed in both the HOPD and ASC settings. Since the onset of the COVID-19 pandemic in 2020, outpatient THA/TKA procedures outnumber inpatient procedures. Given the proportion of THA/TKA procedures that are moving to the outpatient setting, this measure fills a gap by measuring performance at the HOPD/ASC facility level.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure uses Medicare administrative claims data and the Hospital Quality Reporting (HQR) tool. While comprehensive data are unavailable for the ASC and HOPD settings, the measure developer performed a feasibility assessment using PRO data collected from the Center for Medicare and Medicaid Innovation (CMMI) Comprehensive Care for Joint Replacement (CJR) model. Some hospitals that report data for CJR inadvertently submit data on procedures performed in HOPDs, therefore demonstrating the feasibility of implementing this measure in the Hospital OQR program. The

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same data fields would also be collected from ASC facilities.

The 2020-2021 pre-rulemaking cycle considered a hospital-level version of this measure (National Quality Forum (NQF) #3559). When considering the hospital-level version of this measure, MAP members expressed concern regarding data collection and reporting. The developer mentioned that they have worked to mitigate burden by reducing the number of questions to a very small number. That measure was endorsed (NQF #3559) and received a moderate rating for feasibility, suggesting that this HOPD-version is feasible as well.

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 at the facility-level of analysis and was tested in the hospital inpatient acute care facility and HOPD settings. Because the measure is only endorsed at the hospital-level (NQF #3559) and only preliminary data are available for the HOPD setting, comprehensive reliability, validity, and risk-adjustment testing data are unavailable for the ASC and HOPD settings. However, the developer states that it is highly likely that the facility-level reliability of the measure for procedures performed at ASCs and HOPDs will be similar to the inpatient hospital measure due to the same minimum volume threshold (>=25 cases). While both the hospital-level version of the measure and the measure under consideration (MUC) are specified for the same population (Medicare fee-for-service patients 65 years of age and older undergoing elective THA/TKA procedures), the specifications of post-operative data collection vary slightly. The hospital-level measure collects post-operative data 300 to 425 days following surgery, whereas the MUC is specified to collect post-operative data 275 to 425 days following surgery.

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: CMS adopted the hospital-level version of the measure for use in the Hospital IQR program. Prior to mandatory reporting, CMS will conduct two voluntary reporting periods in 2025 and 2026. No unintended consequences to the patient were identified during measure development or testing.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group discussed challenges with implementing the PROM instrument and

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noted the decreased availability of post-operative healthcare services (i.e., physical therapy) in rural settings. Consequently, the Rural Health Advisory Group questioned whether telehealth services could be included in the measure.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concerns regarding patient selection (i.e., bias toward less risky patients) and the impact on health equity.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

The goal of this patient-reported, outcome-based performance measure (PRO-PM) is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. The measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of person-centered care and patient-reported outcome performance measures (PRO-PMs) for the Hospital Outpatient Quality Reporting (OQR) program. The program currently does not include a measure that assesses patient-reported outcomes (PROs) among total hip or knee arthroplasty (THA/TKA) patients at the hospital outpatient department (HOPD) level.

A version of this measure, Centers for Medicare & Medicaid Services' (CMS) Hospital-Level, Risk-Standardized Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA) (CMIT ID 03198), has been adopted for use in the Hospital Inpatient Quality Reporting (IQR) program. This measure, MUC2022-026, is under consideration for use in ambulatory surgical centers (ASCs) for the Ambulatory Surgical Center Quality Reporting (ASCQR) program and in hospital outpatient departments (HOPDs) for the Hospital OQR program. As care moves more toward the ambulatory side, it is important to ensure that procedures and clinical care in hospital settings are of equal high quality and that consumers can compare care across facilities, including HOPDs.

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

THAs and TKAs are common surgeries among Medicare beneficiaries. Estimates suggest that annual THA and TKA procedures performed in the U.S. will reach nearly 2 million by 2030. PROs among THA/TKA patients vary across hospitals. Among inpatient hospitals, the mean distribution of hospitals' risk-standardized improvement rates (RSIRs) ranged from 6.65 to 86.84 percent (median: 66.5 percent; interquartile range: 54.36 to 72.51 percent). This variation across hospitals, which may also apply to HOPDs, suggests opportunities for improvement in quality of care. The measure seeks to improve patient outcomes following elective primary THA/TKA by providing information to patients, physicians, and facilities about facility-level, risk-standardized PROs, such as pain and functional status. This measure is risk-adjusted for patients' comorbid conditions and the goal of the measure is to provide facilities with performance information to implement focused quality improvement efforts.

Preliminary Analysis – MUC2022-027 Facility Commitment to Health Equity (ESRD QIP)

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

Measure Description:

This structural measure assesses facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, individuals with limited English proficiency, rural populations, religious minorities, and people living near or below poverty level. Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.

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 supports the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative's goal to leverage quality measures to promote health equity and close gaps in case, and the CMS National Quality Strategy Goal of advancing health equity. It also addresses a high priority area for future measure consideration—health equity—for the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) by promoting the collection of demographic and social determinants of health information.

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

Yes/No: No

Justification and Notes: The Institute for Healthcare Improvement (IHI) identified five core features of health care organizations that make health equity a core strategy, including making health equity a leader-driven priority, developing structures and processes that support equity, deploying specific strategies to address the multiple determinants of health on which health care organizations can have a direct impact, decreasing institutional racism within the organization, and developing partnerships with community organizations to improve health and equity (Laderman et al., 2016). The five questions for this structural measures are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework for helping health care organizations build a response to health disparities through a focus on data collection, data analysis, culture of equity, quality improvement and interventions.

Nevertheless, there is little empirical evidence directly connecting the elements of the measure to improved patient clinical outcomes.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: While health equity has been identified as a priority for healthcare facilities nationally, most notably in the CMS Meaningful Measures 2.0 initiative, there was no data provided by the developer on care gaps for this measure. While increasing awareness of the role of organizational

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commitment to health equity may be an important starting point, this measure would be strengthened with gap and testing data from dialysis facilities.

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

Yes/No: Yes

Justification and Notes: MAP reviewed a version of this measure as part of the 2021-2022 prerulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System rule.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: No data elements for this measure are in defined fields in electronic sources. The measure under consideration (MUC) can be electronically reported through a web interface. However, it is important to note that in addition to the process for reporting the measure itself, the facility 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 facility'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 facility.

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 developed but not endorsed by a consensus-based entity (CBE) or tested so there is no validity or reliability data for dialysis facilities provided to support this 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: No

Justification and Notes: The developer suggests that for facilities that do not meet the five areas emphasized in this measure, this could create burden to address the measurement area and move

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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 facilities making needed investments in leadership, data and culture to advance equity. We believe the activities outlined in the attestation questions are foundational best practices for advancing health equity for patients and communities.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed support for the measure for advancing access to and quality of care. However, the Rural Health Advisory Group noted that resource challenges exist in rural communities.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concern that this is a "checklist" measure that fails to address health inequities at a systematic level.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.

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

This measure supports the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative's goal of leveraging quality measures to promote health equity and close gaps in care, and the CMS National Quality Strategy Goal of advancing health equity. There are no other health equity measures for this population.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fiscal year

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(FY) 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System rule.

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

Reducing healthcare disparities would represent a substantial benefit to the overall quality of care. However, the literature currently does not closely link this measure to clinical outcomes; likewise, a performance gap at the individual dialysis-facility level on these specific structural elements has not been established in the literature.

MAP conditionally supported MUC2021-106 for rulemaking, and the recommendation for that measure seems relevant for this measure. This measure under consideration (MUC) assesses whether the facility has developed a plan to address health equity issues, has collected and analyzed the data needed to act on that plan, and has evaluated their progress towards attaining their objectives. MAP suggested the information in this measure (when reviewing MUC2021-106) be collected by national survey bodies and quality collaboratives while an improved outcome measure is created.

Preliminary Analysis – MUC2022-027 Facility Commitment to Health Equity (IPFQR)

Program: Inpatient Psychiatric Facility Quality Reporting Program

Measure Description:

This structural measure assesses facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, individuals with limited English proficiency, rural populations, religious minorities, and people living near or below poverty level. Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.

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 supports the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative's goal of leveraging quality measures to promote health equity and close gaps in care, and the CMS National Quality Strategy Goal of advancing health equity. There are no other health equity measures for this population.

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

Yes/No: No

Justification and Notes: The Institute for Healthcare Improvement (IHI) identified five core features of health care organizations that make health equity a core strategy, including making health equity a leader-driven priority, developing structures and processes that support equity, deploying specific strategies to address the multiple determinants of health on which health care organizations can have a direct impact, decreasing institutional racism within the organization, and developing partnerships with community organizations to improve health and equity (Laderman et al., 2016). The five questions for this structural measures are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework for helping health care organizations build a response to health disparities through a focus on data collection, data analysis, culture of equity, quality improvement and interventions.

Nevertheless, there is little empirical evidence directly connecting the elements of the measure to improved patient clinical outcomes.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: While health equity has been identified as a priority for healthcare organizations, most notably in the CMS Meaningful Measures 2.0 initiative, there was no data provided by the developer on care gaps for this measure. While increasing awareness of the important role of organizational commitment to health equity may be a starting point, this measure would be strengthened with gap and testing data from inpatient psychiatric facilities.

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

Yes/No: Yes

Justification and Notes: MAP reviewed a version of this measure as part of the 2021-2022 prerulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System rule.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: No data elements for this measure are in defined fields in electronic sources. The measure under consideration (MUC) can be electronically reported through a web interface. However, it is important to note that in addition to the process for reporting the measure itself, the facility 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 facility'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 facility.

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 developed but not endorsed by a consensus-based entity (CBE) or tested so there is no validity or reliability data provided to support this 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: No

Justification and Notes: The developer suggests that for facilities 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 facilities making needed investments in leadership, data and culture to advance equity. We believe the activities outlined in the attestation questions are foundational best practices for advancing

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health equity for patients and communities.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed support for the measure for advancing access to and quality of care. However, the Rural Health Advisory Group noted that resource challenges exist in rural communities.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concern that this is a "checklist" measure that fails to address health inequities at a systematic level.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.

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

This measure supports the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative's goal of leveraging quality measures to promote health equity and close gaps in care, and the CMS National Quality Strategy Goal of advancing health equity. There are no other health equity measures for this population.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fis cal year (FY) 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System rule.

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

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Reducing healthcare disparities would represent a substantial benefit to the overall quality of care. However, the literature currently does not closely link this measure to clinical outcomes; likewise, a performance gap at the individual dialysis-facility level on these specific structural elements has not been established in the literature.

MAP conditionally supported MUC2021-106 for rulemaking, and the recommendation for that measure seems relevant for this measure. This measure under consideration (MUC) assesses whether the facility has developed a plan to address health equity issues, has collected and analyzed the data needed to act on that plan, and has evaluated their progress towards attaining their objectives. MAP suggested the information in this measure (when reviewing MUC2021-106) be collected by national survey bodies and quality collaboratives while an improved outcome measure is created.

Preliminary Analysis – MUC2022-027 Facility Commitment to Health Equity (PCHQRP)

Program: Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

Measure Description:

This structural measure assesses facility commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, individuals with limited English proficiency, rural populations, religious minorities, and people living near or below poverty level. Facilities will receive one point each for attesting to five different domains of commitment to advancing health equity for a total of five points.

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 supports the Centers for Medicare & Medicaid Services (CMS) Meaningful Measure 2.0 initiative's goal of leveraging quality measures to promote health equity and close gaps in care, and the CMS National Quality Strategy Goal of advancing health equity.

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

Yes/No: No

Justification and Notes: The Institute for Healthcare Improvement (IHI) identified five core features of health care organizations that make health equity a core strategy, including making health equity a leader-driven priority, developing structures and processes that support equity, deploying specific strategies to address the multiple determinants of health on which health care organizations can have a direct impact, decreasing institutional racism within the organization, and developing partnerships with community organizations to improve health and equity (Laderman et al., 2016). The five questions for this structural measures are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework for helping health care organizations build a response to health disparities through a focus on data collection, data analysis, culture of equity, quality improvement and interventions.

Nevertheless, there is little empirical evidence directly connecting the elements of the measure to improved patient clinical outcomes.

Does the measure address a quality challenge?

Yes/No: No

Justification and Notes: While health equity has been identified as a priority for healthcare facilities nationally, most notably in the CMS Meaningful Measures 2.0 initiative, there was no data provided by the developer on care gaps for this measure. While increasing awareness of the important role of organizational commitment to health equity, this measure would be strengthened with gap and testing data from cancer hospitals.

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

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measurement across programs?

Yes/No: Yes

Justification and Notes: MAP reviewed a version of this measure as part of the 2021-2022 prerulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System rule.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: No data elements for this measure are in defined fields in electronic sources. The measure under consideration (MUC) can be electronically reported through a web interface. However, it is important to note that in addition to the process for reporting the measure itself, the facility 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 facility'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 facility.

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 developed but not endorsed by a consensus-based entity (CBE) or tested so there is no reliability or validity data provided to support this 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: No

Justification and Notes: The developer suggests that for facilities 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 facilities making needed investments in leadership, data and culture to advance equity. We believe the activities outlined in the attestation questions are foundational best practices for advancing health equity for patients and communities.

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PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed support for the measure for advancing access to and quality of care. However, the Rural Health Advisory Group noted that resource challenges exist in rural communities.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed concern that this is a "checklist" measure that fails to address health inequities at a systematic level.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.

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

This measure supports the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative's goal of leveraging quality measures to promote health equity and close gaps in care, and the CMS National Quality Strategy Goal of advancing health equity. There are no other health equity measures for this population.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, Hospital Commitment to Health Equity (MUC2021-106), was submitted for the Hospital Inpatient Quality Reporting (IQR) Program. It received a recommendation of Conditional Support for Rulemaking, with the following conditions: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results, and (4) verifying attestation provided by the accountable entities. The measure was finalized for use in the Hospital IQR Program in the fiscal year (FY) 2023 Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System rule.

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

Reducing healthcare disparities would represent a substantial benefit to the overall quality of

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care. However, the literature currently does not closely link this measure to clinical outcomes; likewise, a performance gap at the individual dialysis-facility level on these specific structural elements has not been established in the literature.

MAP conditionally supported MUC2021-106 for rulemaking, and the recommendation for that measure seems relevant for this measure. This measure under consideration (MUC) assesses whether the facility has developed a plan to address health equity issues, has collected and analyzed the data needed to act on that plan, and has evaluated their progress towards attaining their objectives. MAP suggested the information in this measure (when reviewing MUC2021-106) be collected by national survey bodies and quality collaboratives while an improved outcome measure is created.

Preliminary Analysis – MUC2022-050 Screen Positive Rate for Social Drivers of Health (ESRD QIP)

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

Measure Description:

The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients admitted for an inpatient facility stay or that have received established care in the case of dialysis facilities, and who are 18 years or older on the date of admission or date of established care in the case of dialysis facilities, were screened for all five HSRNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

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 examines social determinants of health through the reporting of the percentage of dialysis patients who screened positive for a health-related social need. The measure design supports the measure priority area of the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) to promote measures that expand the collection of social risk factor data as well as the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants.

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

Yes/No: No

Justification and Notes: Research has found an association between social determinants of health and chronic conditions (Boswell Dean et al., 2020; Hill-Briggs et al., 2021), as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (Baker et al., 2021; Khullar et al., 2020). However, there is not a clear connection between screening for social determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017).

The developer cites a U.S. Preventive Services Task Force (USPSTF) guideline on intimate partner violence (IPV) screening that recommends clinicians screen for IPV in women of reproductive age and refer those who screen positive to ongoing support services; this recommendation supports one of the five elements included in the health-related social need screening (i.e., interpersonal safety). However, the recommendation statement notes that the USPSTF "found inadequate direct evidence that screening for IPV can reduce violence, abuse, and physical or mental harms" for that population and did not find sufficient evidence to address the value of screening or interventions for IPV in men and the value of screening for or interventions for abuse and neglect in older or vulnerable adults (USPSTF, 2018). Systematic reviews of the impacts of IPV screening have shown that screening has not demonstrated improved health outcomes (Feltner et al., 2018; Weil et al., 2022).

The developer did not cite evidence or guidelines for how providers and facilities may impact their screen positive rate related to the other four health-related social needs. While the measure is designed to impact an important quality topic, the evidence base submitted is insufficient that the measure as

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specified will have a positive impact on patient outcomes.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Addressing and reducing the effects of social determinants of health has become a top priority of major healthcare stakeholders in recent years (Lew and Sommers, 2022; National Academies of Sciences, Engineering, and Medicine, 2017). A recent study found that only 24 percent of hospitals screen for the social determinants identified by the measure, though the study did not provide a breakdown for dialysis facilities (Fraze et al., 2019). The measure developer provided data from the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities (AHC) Pilot demonstrating that 33 percent of patients screened positive for at least one social need, though they did not provide information for the subset of how many dialysis patients screened positive or data on how positive screening rates differed between facilities. The measure also does not address follow-up after a positive screening. Given the overall low performance across other care settings, it is reasonable to assume that screening for social drivers of health is a quality challenge in the ESRD care setting as well.

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 ESRD QIP does not currently have measures that address social determinants of health, so the measure would not cause duplication within the measure set. However, the value of the measure to patients is currently unclear, especially as the measure does not track if patients who screen positive are connected to services.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, MUC2021-134, was submitted for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) endorsement by a consensus-based entity (CBE) to address reliability and validity concerns; and (2) the results of the measure not being used to penalize or criticize health care providers under the two programs.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified, and the developer stated that providers can collect screening data for the measure electronically, with the only additional demographic information required being the patient's age. While the measure is not currently in use in federal programs, the developer noted that providers in the AHC Pilot have used the same screening tool to screen nearly one

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million patients in 21 states.

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 developer has not yet submitted the measure for endorsement by a consensus-based entity (CBE). The measure is fully developed, and the developer has provided full specifications for the measure in the setting assessed by the ESRD QIP. The developer submitted validity testing for the food insecurity items in the screening tool (<u>Gundersen et al., 2017</u>; <u>Hager et al., 2010</u>), as well as an analysis of inter-rater reliability between the measure's screening tool and the Your Current Life Situation tool (<u>Lewis et al., 2020</u>). However, the developer did not submit reliability or validity testing data for the measure as specified in the target population of dialysis patients.

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's screening tool was used in the AHC Pilot. The developer noted that the Year 1 evaluation of that pilot found that a lack of community resources may result in health systems that are not equipped to act on the results of screening. The developer also noted that the evaluation found that this challenge was a primary barrier to connecting beneficiaries to resources (RTI International, 2020). However, the developer also noted that 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.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group highlighted potential reporting challenges, specifically noting the potential masking of health disparities that are underrepresented in some areas. The Rural Health Advisory Group raised that sample size and populations served may be an issue. The Rural Health Advisory Group noted that it would be useful for rural health considerations for CMS to provide statistical significance (since statistical tools are not readily available) to facilitate evaluating outcomes. The Rural Health Advisory Group discussed the importance of having community resources available for patients and families. Finally, the Rural Health Advisory Group expressed that the measure seeks to advance the drivers of health and that measures serve as a starting point to determine where screening is occurring.

MAP Health Equity Advisory Group Input:

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The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting of the measure. Additionally, the Health Equity Advisory Group raised concerns about repeatedly asking patients the same questions in different health care settings.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement by a consensus-based entity (CBE) to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across hospitals).

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

This measure captures the percentage of patients who screen positive for at least one of five health-related social needs. The measure would be the first measure in the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) measure set to implement screening for social determinants of health, which would support both a Meaningful Measures 2.0 priority to develop and implement measures that reflect social and economic determinants and a program priority to promote measures that expand the collection of social risk factor data for future measure development.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-134) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) endorsement by a consensus-based entity (CBE) to address reliability and validity concerns; and (2) the results of the measure not being used to penalize or criticize health care providers under the two programs.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

MAP supported the importance of the measure for identifying facilities that may need more resources and for quality improvement purposes. MAP members thought the measure could encourage facilities to engage with their communities. However, other MAP members had concerns that the measure does not reflect quality of care, but rather a facility's patient population mix, and that consumers could misunderstand how to interpret the measure's results. MAP members encouraged presentation of the results in a way that provides context for consumers.

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

Research has found an association between social determinants of health and chronic conditions (<u>Boswell Dean et al., 2020</u>; <u>Hill-Briggs et al., 2021</u>), as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (<u>Baker et al., 2021</u>; <u>Khullar et al., 2020</u>). However, there is not a clear connection between screening for social

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determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017).

MAP noted that this measure to document positive screen rates for social drivers of health is an important first step to addressing important social drivers of health outcomes and may be used to stratify other data, leading to the reallocation of financial resources in the future. However, MAP also expressed concern that the positivity rate may be challenging for consumers to interpret when publicly reported.

Preliminary Analysis – MUC2022-050 Screen Positive Rate for Social Drivers of Health (IPFQR)

Program: Inpatient Psychiatric Facility Quality Reporting Program

Measure Description:

The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients admitted for an inpatient facility stay or that have received established care in the case of dialysis facilities, and who are 18 years or older on the date of admission or date of established care in the case of dialysis facilities, were screened for all five HSRNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

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 examines social determinants of health through the reporting of the percentage of patients admitted to an inpatient psychiatric facility who screened positive for a health-related social need. The measure design supports the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants.

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

Yes/No: No

Justification and Notes: Research has found an association between social determinants of health and chronic conditions (Boswell Dean et al., 2020; Hill-Briggs et al., 2021) as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (Baker et al., 2021; Khullar et al., 2020). However, there is not a clear connection between screening for social determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017).

The developer cites a U.S. Preventive Services Task Force (USPSTF) guideline on intimate partner violence (IPV) screening that recommends clinicians screen for IPV in women of reproductive age and refer those who screen positive to ongoing support services; this recommendation supports one of the five elements included in the health-related social need screening (i.e., interpersonal violence). However, the recommendation statement notes that the USPSTF "found inadequate direct evidence that screening for IPV can reduce violence, abuse, and physical or mental harms" for that population and did not find sufficient evidence to address the value of screening or interventions for IPV in men and the value of screening for or interventions for abuse and neglect in older or vulnerable adults (USPSTF, 2018). Systematic reviews of the impacts of IPV screening have shown that screening has not demonstrated improved health outcomes (Feltner et al., 2018; Weil et al., 2022).

The developer did not cite evidence or guidelines for how providers and facilities may impact their screen positive rate related to the other four health-related social needs. While the measure is designed to impact an important quality topic, the evidence base submitted is insufficient that the measure as specified will have a positive impact on patient outcomes.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Addressing and reducing the effects of social determinants of health has become a top priority of major healthcare stakeholders in recent years (Lew and Sommers, 2022;
National Academies of Sciences, Engineering, and Medicine, 2017). A recent study found that only 24 percent of hospitals screen for the social determinants identified by the measure, though the study did not provide a breakdown for inpatient psychiatric facilities (Fraze et al., 2019). The measure developer provided data from the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities (AHC) Pilot demonstrating that 33 percent of patients screened positive for at least one social need, though they did not provide information for the subset of how many patients at inpatient psychiatric facilities screened positive or data on how positive screening rates differed between facilities. The measure also does not address follow-up after a positive screening. Given the overall low performance across other care settings, it is reasonable to assume that screening for social drivers of health is a quality challenge in inpatient psychiatric facilities as well.

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 Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program does not currently have measures that address social determinants of health, so the measure would not cause duplication within the measure set. However, the value of the measure to patients is currently unclear, especially as the measure does not track if patients who screen positive are connected to services.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, MUC2021-134, was submitted for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) endorsement by a consensus-based entity (CBE) to address reliability and validity concerns; and (2) the results of the measure not being used to penalize or criticize health care providers under the two programs.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified, and the developer stated that providers can collect screening data for the measure electronically, with the only additional demographic information required being the patient's age. While the measure is not currently in use in federal programs, the developers noted that providers in the AHC Pilot have used the same screening tool to screen nearly one million patients in 21 states.

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 developer has not yet submitted the measure for endorsement by a consensus-based entity (CBE). The measure is fully developed, and the developer has provided full specifications for the measure in the setting assessed by the IPFQR Program. The developer submitted validity testing for the food insecurity items in the screening tool (Gundersen et al., 2017; Hager et al., 2010), as well as an analysis of inter-rater reliability between the measure's screening tool and the Your Current Life Situation tool (Lewis et al., 2020). However, the developer did not submit reliability or validity testing data for the measure as specified in the target population of patients at inpatient psychiatric facilities.

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's screening tool was used in the AHC Pilot. The developer noted that the Year 1 evaluation of that pilot found that a lack of community resources may result in health systems that are not equipped to act on the results of screening. The developer also noted that the evaluation found that this challenge was a primary barrier to connecting beneficiaries to resources (RTI International, 2020). However, the developer also noted that 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.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group highlighted potential reporting challenges, specifically noting the potential masking of health disparities that are underrepresented in some areas. The Rural Health Advisory Group raised that sample size and populations served may be an issue. The Rural Health Advisory Group noted that it would be useful for rural health considerations for CMS to provide statistical significance (since statistical tools are not readily available) to facilitate evaluating outcomes. The Rural Health Advisory Group discussed the importance of having community resources available for patients and families. Finally, the Rural Health Advisory Group expressed that the measure seeks to advance the drivers of health and that measures serve as a starting point to determine where screening is occurring.

MAP Health Equity Advisory Group Input:

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The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting of the measure. Additionally, the Health Equity Advisory Group raised concerns about repeatedly asking patients the same questions in different health care settings.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement by a consensus-based entity (CBE) to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across hospitals).

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

This measure captures the percentage of patients who screen positive for at least one of five health-related social needs. The measure would be the first measure in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program measure set to implement screening for social determinants of health, which would support a Meaningful Measures 2.0 priority to develop and implement measures that reflect social and economic determinants.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-134) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) endorsement by a consensus-based entity (CBE) to address reliability and validity concerns; and (2) the results of the measure not being used to penalize or criticize health care providers under the two programs.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

MAP supported the importance of the measure for identifying facilities that may need more resources and for quality improvement purposes. MAP members thought the measure could encourage facilities to engage with their communities. However, other MAP members had concerns that the measure does not reflect quality of care, but rather a facility's patient population mix, and that consumers could misunderstand how to interpret the measure's results. MAP members encouraged presentation of the results in a way that provides context for consumers.

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

Research has found an association between social determinants of health and chronic conditions (<u>Boswell Dean et al., 2020</u>; <u>Hill-Briggs et al., 2021</u>), as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (<u>Baker et al., 2021</u>; <u>Khullar et al., 2020</u>). However, there is not a clear connection between screening for social

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determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017).

MAP noted that this measure to document positive screen rates for social drivers of health is an important first step to addressing important social drivers of health outcomes and may be used to stratify other data, leading to the reallocation of financial resources in the future. However, MAP also expressed concern that the positivity rate may be challenging for consumers to interpret when publicly reported.

Preliminary Analysis – MUC2022-050 Screen Positive Rate for Social Drivers of Health (PCHQRP)

Program: Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

Measure Description:

The Screen Positive Rate for Social Drivers of Health is a structural measure that provides information on the percent of patients admitted for an inpatient facility stay or that have received established care in the case of dialysis facilities, and who are 18 years or older on the date of admission or date of established care in the case of dialysis facilities, were screened for all five HSRNs, and who screen positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation problems, utility difficulties, or interpersonal safety.

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 examines social determinants of health through the reporting of the percentage of patients admitted to an eligible cancer hospital who screened positive for a health-related social need. The measure design supports the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants.

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

Yes/No: No

Justification and Notes: Research has found an association between social determinants of health and chronic conditions (Boswell Dean et al., 2020; Hill-Briggs et al., 2021) as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (Baker et al., 2021; Khullar et al., 2020). However, there is not a clear connection between screening for social determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017).

The developer cites a U.S. Preventive Services Task Force (USPSTF) guideline on intimate partner violence (IPV) screening that recommends clinicians screen for IPV in women of reproductive age and refer those who screen positive to ongoing support services; this recommendation supports one of the five elements included in the health-related social need screening (i.e., interpersonal violence). However, the recommendation statement notes that the USPSTF "found inadequate direct evidence that screening for IPV can reduce violence, abuse, and physical or mental harms" for that population and did not find sufficient evidence to address the value of screening or interventions for IPV in men and the value of screening for or interventions for abuse and neglect in older or vulnerable adults (USPSTF, 2018). Systematic reviews of the impacts of IPV screening have shown that screening has not demonstrated improved health outcomes (Feltner et al., 2018; Weil et al., 2022).

The developer did not cite evidence or guidelines for how providers and facilities may impact their screen positive rate related to the other four health-related social needs. While the measure is designed to impact an important quality topic, the evidence base submitted is insufficient that the measure as specified will have a positive impact on patient outcomes.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Addressing and reducing the effects of social determinants of health has become a top priority of major healthcare stakeholders in recent years (Lew and Sommers, 2022; National Academies of Sciences, Engineering, and Medicine, 2017). A recent study found that only 24 percent of hospitals screen for the social determinants identified by the measure, though the study did not provide a breakdown for cancer hospitals (Fraze et al., 2019). The measure developer provided data from the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities (AHC) Pilot demonstrating that 33 percent of patients screened positive for at least one social need, though they did not provide information for the subset of how many patients at participating cancer hospitals screened positive or data on how positive screening rates differed between participating cancer hospitals. The measure also does not address follow-up after a positive screening. Given the overall low performance across other care settings, it is reasonable to assume that screening for social drivers of health is a quality challenge in the cancer hospital care setting as well.

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 Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program does not currently have measures that address social determinants of health, so the measure would not cause duplication within the measure set. However, the value of the measure to patients is currently unclear, especially as the measure does not track if patients who screen positive are connected to services.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle. The measure, MUC2021-134, was submitted for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) endorsement by a consensus-based entity (CBE) to address reliability and validity concerns; and (2) the results of the measure not being used to penalize or criticize health care providers under the two programs.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified, and the developer stated that providers can collect screening data for the measure electronically, with the only additional demographic information required being the patient's age. While the measure is not currently in use in federal programs, the developers noted that providers in the AHC Pilot have used the same screening tool to screen nearly one

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million patients in 21 states.

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 developer has not yet submitted the measure for endorsement by a consensus-based entity (CBE). The measure is fully developed, and the developer has provided full specifications for the measure in the setting assessed by the PCHQR Program. The developer submitted validity testing for the food insecurity items in the screening tool (Gundersen et al., 2017; Hager et al., 2010), as well as an analysis of inter-rater reliability between the measure's screening tool and the Your Current Life Situation tool (Lewis et al., 2020). However, the developer did not submit reliability or validity testing data for the measure as specified in the target population of patients at qualified cancer hospitals.

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's screening tool was used in the AHC Pilot. The developer noted that the Year 1 evaluation of that pilot found that a lack of community resources may result in health systems that are not equipped to act on the results of screening. The developer also noted that the evaluation found that this challenge was a primary barrier to connecting beneficiaries to resources (RTI International, 2020). However, the developer also noted that 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.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group highlighted potential reporting challenges, specifically noting the potential masking of health disparities that are underrepresented in some areas. The Rural Health Advisory Group raised that sample size and populations served may be an issue. The Rural Health Advisory Group noted that it would be useful for rural health considerations for CMS to provide statistical significance (since statistical tools are not readily available) to facilitate evaluating outcomes. The Rural Health Advisory Group discussed the importance of having community resources available for patients and families. Finally, the Rural Health Advisory Group expressed that the measure seeks to advance the drivers of health and that measures serve as a starting point to determine where screening is occurring.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting of the measure. Additionally, the Health Equity Advisory Group raised concerns about repeatedly asking patients the same questions in different health care settings.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement by a consensus-based entity (CBE) to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across hospitals).

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

This measure captures the percentage of patients who screen positive for at least one of five health-related social needs. The measure would be the first measure in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program measure set to implement screening for social determinants of health, which would support a Meaningful Measures 2.0 priority to develop and implement measures that reflect social and economic determinants.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-134) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) endorsement by a consensus-based entity (CBE) to address reliability and validity concerns; and (2) the results of the measure not being used to penalize or criticize health care providers under the two programs.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

MAP supported the importance of the measure for identifying facilities that may need more resources and for quality improvement purposes. MAP members thought the measure could encourage facilities to engage with their communities. However, other MAP members had concerns that the measure does not reflect quality of care, but rather a facility's patient population mix, and that consumers could misunderstand how to interpret the measure's results. MAP members encouraged presentation of the results in a way that provides context for consumers.

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

Research has found an association between social determinants of health and chronic conditions (<u>Boswell Dean et al., 2020</u>; <u>Hill-Briggs et al., 2021</u>), as well as an association between providers with patient populations facing social risks and their poor performance on healthcare metrics (<u>Baker et al.</u>,

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<u>2021</u>; <u>Khullar et al., 2020</u>). However, there is not a clear connection between screening for social determinants and improving patient outcomes and there needs to be additional research on the topic (Davidson et al., 2017).

MAP noted that this measure to document positive screen rates for social drivers of health is an important first step to addressing important social drivers of health outcomes and may be used to stratify other data, leading to the reallocation of financial resources in the future. However, MAP also expressed concern that the positivity rate may be challenging for consumers to interpret when publicly reported.

Preliminary Analysis – MUC2022-053 Screening for Social Drivers of Health (ESRD QIP)

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

Measure Description:

The Screening for Social Drivers of Health measure assesses the total number of patients, aged 18 years and older, screened for social risk factors (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during an inpatient facility stay, or during established care in the case of dialysis facilities. The measure cohort includes patients who are admitted to an inpatient facility or who have established care in the case of dialysis facilities and are 18 years or older on the date of admission or on the date of established care in the case of 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: The measure design supports the measure priority area of the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) to promote measures that expand the collection of social risk factor data as well as the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants. There are no other measures in the ESRD Quality Incentive program that address equity.

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

Yes/No: Yes

Justification and Notes: Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the physical environment (Hood et al, 2017). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (Stafford and Wood, 2017), food (Staren, 2020), and other needs screened for by the tool cited in this measure (Davidson et al, 2020). The developer attests that screening for these socioeconomic factors is consistent with guidelines implemented by the American Academy of Pediatrics (AAP), the American Academy of Family Practitioners (AAFP), and guidance by the U.S. Preventative Services Task Force (USPSTF). The developer cites a specific USPSTF guideline that concludes screening for intimate partner violence (IPV) in women of reproductive age and providing or referring women who screen positive to ongoing support services has a moderate net benefit (USPSTF, 2018). However, the recommendation by USPSTF also states that "the USPSTF found inadequate direct evidence that screening for IPV can reduce violence, abuse, and physical or mental harms" (USPSTF, 2018). Additionally, the recommendation for screening only applies to women of reproductive age as the evidence demonstrating a benefit of ongoing support services is predominantly found in pregnant or postpartum women (USPSTF, 2018). Systematic reviews of the evidence on IPV screening have shown that screening has not demonstrated a reduction in IPV exposure or improvement in quality of life (Feltner et al, 2018).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer states that identifying social and economic determinants of health has become a priority by organizations in healthcare such as Centers for Medicare & Medicaid (CMS), Office of the Assistant Secretary for Planning and Evaluation (ASPE), National Quality Forum (NQF), and National Committee for Quality Assurance (NCQA). The developer cites a study from 2019 which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (Fraze et al, 2019), indicating a gap in care provided. The developers provided data from the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities (AHC) program that found that 34 percent of screened patients had one or more domains defined in the tool. It is not clear how many of those that were screened were dialysis patients, however, the screenings took place in a variety of settings such as hospital inpatient, emergency department, primary care, and clinic settings.

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 ESRD QIP. The developer reports that of the 3,162 patients consulted on the measure, 2,441 indicated that the tool is meaningful (around 77 percent). Additionally, of the 10,078 clinicians consulted on the measure, 8,800 indicated that the tool is meaningful (around 87 percent).

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-136) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified. The developer attests that to report the measure, providers must collect the total number of patients and the number of patients who were screened with only patient age needed for demographic information. The developer states that the screening tool can be electronically collected and recorded so all data points needed for reporting should be available to providers. The measure has been in use in the AHC pilot program. The developer further notes that within the AHC pilot program, the measure has been in use in 21 states across the U.S. 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)?

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Yes/No: No

Justification and Notes: The developer has not yet submitted the measure for endorsement by a consensus-based entity (CBE). The measure is fully developed. The measure developer submitted interrater reliability testing between this measure and the Your Current Life Situation tool. The developer attests that the Kappas calculated between the AHC and YCLS tool were greater than 0.60 except for housing quality which had a Kappa of 0.52 (Lewis et al, 2020). For validity testing, the developer submitted validity testing for the food insecurity items in the screening tool noting that the results suggest the screening for food insecurity was sensitive, specific, and valid (Hager et al, 2010 and Gundersen et al, 2017). Further, the developer notes an additional study submitted for validity testing demonstrated that a reported social risk on the AHC and YCLS measures was strongly associated with having a fair or poor self-rated health (Lewis et al, 2020). However, it is unclear if specific specifications, reliability, and validity testing is sufficient for dialysis facilities.

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 measure has been in use in the AHC pilot program. The developer states that a potential unintended consequence of the measure is that those who use the screening tool will not be equipped to act due to a lack of community resources. The developer further notes that this challenge was specifically noted as the primary barrier connecting beneficiaries to resources in the AHC one year evaluation. However, the developer attests that there are well-documented and well-tested additional tools, infrastructure, and investments that can implemented to support those who implement this measure.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group highlighted potential reporting challenges, specifically noting the potential masking of health disparities that are underrepresented in some areas. The Rural Health Advisory Group raised that sample size and populations served may be an issue. The Rural Health Advisory Group noted that it would be useful for rural health considerations for CMS to provide statistical significance (since statistical tools are not readily available) to facilitate evaluating outcomes. The Rural Health Advisory Group discussed the importance of having community resources available for patients and families. Finally, the Rural Health Advisory Group expressed that the measure seeks to advance the drivers of health and that measures serve as a starting point to determine where screening is occurring.

MAP Health Equity Advisory Group Input:

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The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting of the measure. Additionally, the Health Equity Advisory Group raised concerns about repeatedly asking patients the same questions in different health care settings.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

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

This measure captures those who are screened for five social determinants of health domains (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during their facility stay or during established care. There are no other measures in the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) measure set that implement screening for social determinants of health. The inclusion of this measure would support the goals laid out in the Meaningful Measures 2.0 framework as well as the program priority of inclusion of health equity measures.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-136) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

MAP expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue for patients. In particular, MAP noted that patients may be screened multiple times around these sensitive topics, which could be an issue. However, MAP also recognized that patients' social risk factors may change over time, so repeat screening may be necessary. Overall, MAP noted there needs to be an awareness of the sensitivity of screening for these factors.

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

The developer cites a study from 2019 which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (Fraze et al, 2019), indicating a gap in care provided.

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Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the physical environment (<u>Hood et al, 2017</u>). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (<u>Stafford and Wood, 2017</u>), food (<u>Staren, 2020</u>), and other needs screened for by the tool cited in this measure (<u>Davidson et al, 2020</u>). The developer attests that screening for these socioeconomic factors is consistent with guidelines implemented by the <u>American Academy of Pediatrics (AAP)</u>, the <u>American Academy of Family Physicians (AAFP)</u>, and guidance by the <u>U.S. Preventive Services Task Force (USPSTF)</u>.

Preliminary Analysis – MUC2022-053 Screening for Social Drivers of Health (IPFQR)

Program: Inpatient Psychiatric Facility Quality Reporting Program

Measure Description:

The Screening for Social Drivers of Health measure assesses the total number of patients, aged 18 years and older, screened for social risk factors (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during an inpatient facility stay, or during established care in the case of dialysis facilities. The measure cohort includes patients who are admitted to an inpatient facility or who have established care in the case of dialysis facilities and are 18 years or older on the date of admission or on the date of established care in the case of 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: There are no other measures in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program that address equity. The measure design supports the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants.

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

Yes/No: Yes

Justification and Notes: Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the physical environment (Hood et al, 2017). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (Stafford and Wood, 2017), food (Staren, 2020), and other needs screened for by the tool cited in this measure (Davidson et al, 2020). The developer attests that screening for these socioeconomic factors is consistent with guidelines implemented by the American Academy of Pediatrics (AAP), the American Academy of Family Practitioners (AAFP), and guidance by the U.S. Preventative Services Task Force (USPSTF). The developer cites a specific USPSTF guideline that concludes screening for intimate partner violence (IPV) in women of reproductive age and providing or referring women who screen positive to ongoing support services has a moderate net benefit (USPSTF, 2018). However, the recommendation by USPSTF also states that "the USPSTF found inadequate direct evidence that screening for IPV can reduce violence, abuse, and physical or mental harms" (USPSTF, 2018). Additionally, the recommendation for screening only applies to women of reproductive age as the evidence demonstrating a benefit of ongoing support services is predominantly found in pregnant or postpartum women (USPSTF, 2018). Systematic reviews of the evidence on IPV screening have shown that screening has not demonstrated a reduction in IPV exposure or improvement in quality of life (Feltner et al, 2018).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer states that identifying social and economic determinants of health has become a priority by organizations in healthcare such as Centers for Medicare & Medicaid

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(CMS), Office of the Assistant Secretary for Planning and Evaluation (ASPE), National Quality Forum (NQF), and National Committee for Quality Assurance (NCQA). The developer cites a study from 2019 which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (Fraze et al, 2019), indicating a gap in care provided. The developers provided data from the Accountable Health Communities (AHC) program that found that 34 percent of screened patients had one or more domains defined in the tool. It is not clear how many of those that were screened were inpatient psychiatric patients, however, the screenings took place in a variety of settings such as hospital inpatient, emergency department, primary care, and clinic settings.

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 IPFQR program. The developer reports that of the 3,162 patients consulted on the measure, 2,441 indicated that the tool is meaningful (around 77 percent). Additionally, of the 10,078 clinicians consulted on the measure, 8,800 indicated that the tool is meaningful (around 87 percent).

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-136) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified. The developer attests that to report the measure, providers must collect the total number of patients and the number of patients who were screened with only patient age needed for demographic information. The developer states that the screening tool can be electronically collected and recorded so all data points needed for reporting should be available to providers. The measure has been in use in the AHC pilot program. The developer further notes that within the AHC pilot program, the measure has been in use in 21 states across the U.S. 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

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Justification and Notes: The developer has not yet submitted the measure for endorsement by a consensus-based entity (CBE). The measure is fully developed. The measure developer submitted interrater reliability testing between this measure and the Your Current Life Situation tool. The developer attests that the Kappas calculated between the AHC and YCLS tool were greater than 0.60 except for housing quality which had a Kappa of 0.52 (Lewis et al, 2020). For validity testing, the developer submitted validity testing for the food insecurity items in the screening tool noting that the results suggest the screening for food insecurity was sensitive, specific, and valid (Hager et al, 2010) and Gundersen et al, 2017). Further, the developer notes an additional study submitted for validity testing demonstrated that a reported social risk on the AHC and YCLS measures was strongly associated with having a fair or poor self-rated health (Lewis et al, 2020). However, it is unclear if specific specifications, reliability, and validity testing is sufficient for inpatient psychiatric facilities.

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 measure has been in use in the AHC pilot program. The developer states that a potential unintended consequence of the measure is that those who use the screening tool will not be equipped to act due to a lack of community resources. The developer further notes that this challenge was specifically noted as the primary barrier connecting beneficiaries to resources in the AHC one year evaluation. However, the developer attests that there are well-documented and well-tested additional tools, infrastructure, and investments that can implemented to support those who implement this measure.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group highlighted potential reporting challenges, specifically noting the potential masking of health disparities that are underrepresented in some areas. The Rural Health Advisory Group raised that sample size and populations served may be an issue. The Rural Health Advisory Group noted that it would be useful for rural health considerations for CMS to provide statistical significance (since statistical tools are not readily available) to facilitate evaluating outcomes. The Rural Health Advisory Group discussed the importance of having community resources available for patients and families. Finally, the Rural Health Advisory Group expressed that the measure seeks to advance the drivers of health and that measures serve as a starting point to determine where screening is occurring.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed support for the collection of data related to social health

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drivers, but raised concerns regarding public reporting of the measure. Additionally, the Health Equity Advisory Group raised concerns about repeatedly asking patients the same questions in different health care settings.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

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

This measure captures those who are screened for five social determinants of health domains (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during their facility stay or during established care. There are no other measures in the for Inpatient Psychiatric Facility Quality Reporting (IPFQR) program measure set that implement screening for social determinants of health. The inclusion of this measure would support the goals laid out in the Meaningful Measures 2.0 framework.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-136) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

MAP expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue for patients. In particular, MAP noted that patients may be screened multiple times around these sensitive topics, which could be an issue. However, MAP also recognized that patients' social risk factors may change over time, so repeat screening may be necessary. Overall, MAP noted there needs to be an awareness of the sensitivity of screening for these factors.

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

The developer cites a study from 2019 which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (<u>Fraze et al, 2019</u>), indicating a gap in care provided.

Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the

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physical environment (<u>Hood et al, 2017</u>). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (<u>Stafford and Wood, 2017</u>), food (<u>Staren, 2020</u>), and other needs screened for by the tool cited in this measure (<u>Davidson et al, 2020</u>). The developer attests that screening for these socioeconomic factors is consistent with guidelines implemented by the <u>American Academy of Pediatrics (AAP)</u>, the <u>American Academy of Family Physicians (AAFP)</u>, and guidance by the <u>U.S. Preventive Services Task Force (USPSTF)</u>.

Preliminary Analysis – MUC2022-053 Screening for Social Drivers of Health (PCHQRP)

Program: Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

Measure Description:

The Screening for Social Drivers of Health measure assesses the total number of patients, aged 18 years and older, screened for social risk factors (specifically, food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during an inpatient facility stay, or during established care in the case of dialysis facilities. The measure cohort includes patients who are admitted to an inpatient facility or who have established care in the case of dialysis facilities and are 18 years or older on the date of admission or on the date of established care in the case of 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: There are no other measures in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) program that address equity. The measure design supports the Meaningful Measure 2.0 priority to develop and implement measures that reflect social and economic determinants.

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

Yes/No: Yes

Justification and Notes: Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the physical environment (Hood et al, 2017). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (Stafford and Wood, 2017), food (Staren, 2020), and other needs screened for by the tool cited in this measure (Davidson et al, 2020). The developer attests that screening for these socioeconomic factors is consistent with guidelines implemented by the American Academy of Pediatrics (AAP), the American Academy of Family Practitioners (AAFP), and guidance by the U.S. Preventative Services Task Force (USPSTF). The developer cites a specific USPSTF guideline that concludes screening for intimate partner violence (IPV) in women of reproductive age and providing or referring women who screen positive to ongoing support services has a moderate net benefit (USPSTF, 2018). However, the recommendation by USPSTF also states that "the USPSTF found inadequate direct evidence that screening for IPV can reduce violence, abuse, and physical or mental harms" (USPSTF, 2018). Additionally, the recommendation for screening only applies to women of reproductive age as the evidence demonstrating a benefit of ongoing support services is predominantly found in pregnant or postpartum women (USPSTF, 2018). Systematic reviews of the evidence on IPV screening have shown that screening has not demonstrated a reduction in IPV exposure or improvement in quality of life (Feltner et al, 2018).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: The developer states that identifying social and economic determinants of

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health has become a priority by organizations in healthcare such as Centers for Medicare & Medicaid (CMS), Office of the Assistant Secretary for Planning and Evaluation (ASPE), National Quality Forum (NQF), and National Committee for Quality Assurance (NCQA). The developer cites a study from 2019 which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (Fraze et al, 2019), indicating a gap in care provided. The developers provided data from the Center for Medicare & Medicaid Innovation (CMMI) Accountable Health Communities (AHC) program that found that 34 percent of screened patients had one or more domains defined in the tool. It is not clear how many of those that were screened were cancer patients, however, the screenings took place in a variety of settings such as hospital inpatient, emergency department, primary care, and clinic settings.

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 PCHQR program. The developer reports that of the 3,162 patients consulted on the measure, 2,441 indicated that the tool is meaningful (around 77 percent). Additionally, of the 10,078 clinicians consulted on the measure, 8,800 indicated that the tool is meaningful (around 87 percent).

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-136) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully specified. The developer attests that to report the measure, providers must collect the total number of patients and the number of patients who were screened with only patient age needed for demographic information. The developer states that the screening tool can be electronically collected and recorded so all data points needed for reporting should be available to providers. The measure has been in use in the AHC pilot program. The developer further notes that within the AHC pilot program, the measure has been in use in 21 states across the U.S. 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 developer has not yet submitted the measure for endorsement by a consensus-based entity (CBE). The measure is fully developed. The measure developer submitted interrater reliability testing between this measure and the Your Current Life Situation tool. The developer attests that the Kappas calculated between the AHC and YCLS tool were greater than 0.60 except for housing quality which had a Kappa of 0.52 (Lewis et al, 2020). For validity testing, the developer submitted validity testing for the food insecurity items in the screening tool noting that the results suggest the screening for food insecurity was sensitive, specific, and valid (Hager et al, 2010) and Gundersen et al, 2017). Further, the developer notes an additional study submitted for validity testing demonstrated that a reported social risk on the AHC and YCLS measures was strongly associated with having a fair or poor self-rated health (Lewis et al, 2020). However, it is unclear if specific specifications, reliability, and validity testing is sufficient for facilities included in the PCHQR program.

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 measure has been in use in the AHC pilot program. The developer states that a potential unintended consequence of the measure is that those who use the screening tool will not be equipped to act due to a lack of community resources. The developer further notes that this challenge was specifically noted as the primary barrier connecting beneficiaries to resources in the AHC one year evaluation. However, the developer attests that there are well-documented and well-tested additional tools, infrastructure, and investments that can implemented to support those who implement this measure.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group highlighted potential reporting challenges, specifically noting the potential masking of health disparities that are underrepresented in some areas. The Rural Health Advisory Group raised that sample size and populations served may be an issue. The Rural Health Advisory Group noted that it would be useful for rural health considerations for CMS to provide statistical significance (since statistical tools are not readily available) to facilitate evaluating outcomes. The Rural Health Advisory Group discussed the importance of having community resources available for patients and families. Finally, the Rural Health Advisory Group expressed that the measure seeks to advance the drivers of health and that measures serve as a starting point to determine where screening is occurring.

MAP Health Equity Advisory Group Input:

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The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting of the measure. Additionally, the Health Equity Advisory Group raised concerns about repeatedly asking patients the same questions in different health care settings.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

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

This measure captures those who are screened for five social determinants of health domains (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) during their facility stay or during established care. There are no other measures in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) program measure set that implement screening for social determinants of health. The inclusion of this measure would support the goals laid out in the Meaningful Measures 2.0 framework.

The Measure Applications Partnership (MAP) reviewed a version of this measure as part of the 2021-2022 pre-rulemaking cycle (MUC2021-136) for the Hospital Inpatient Quality Reporting (IQR) Program and the Merit-based Incentive Payment System (MIPS). It received a recommendation of Conditional Support for Rulemaking for both programs, with the following conditions: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.

For the 2022-2023 pre-rulemaking cycle, this measure is being proposed for the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program, End-Stage Renal Disease Quality Incentive Program (ESRD QIP), and Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. Using this measure in multiple programs will align goals related to health equity infrastructure across the healthcare system. The developer has also submitted Screening for Social Drivers of Health (MUC2022-053) for the same three programs.

MAP expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue for patients. In particular, MAP noted that patients may be screened multiple times around these sensitive topics, which could be an issue. However, MAP also recognized that patients' social risk factors may change over time, so repeat screening may be necessary. Overall, MAP noted there needs to be an awareness of the sensitivity of screening for these factors.

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

The developer cites a study from 2019 which found that only 24 percent of hospitals and 16 percent of physician practices reported screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence (Fraze et al, 2019), indicating a gap in care provided.

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Health outcomes are around 80 percent driven by socioeconomic factors, health behaviors, and the physical environment (<u>Hood et al, 2017</u>). Several studies provided by the measure developer identify a relationship between health outcomes and socioeconomic factors including, but not limited to, housing (<u>Stafford and Wood, 2017</u>), food (<u>Staren, 2020</u>), and other needs screened for by the tool cited in this measure (<u>Davidson et al, 2020</u>). The developer attests that screening for these socioeconomic factors is consistent with guidelines implemented by the <u>American Academy of Pediatrics (AAP)</u>, the <u>American Academy of Family Physicians (AAFP)</u>, and guidance by the <u>U.S. Preventive Services Task Force (USPSTF)</u>.

Preliminary Analysis – MUC2022-064 Hospital Harm - Pressure Injury (Hospital IQR)

Program: Hospital Inpatient Quality Reporting Program

Measure Description:

The proportion of inpatient hospitalizations for patients 18 years of age or older at the start of the encounter, who suffer the harm of developing a new stage 2, stage 3, stage 4, deep tissue, or unstageable pressure injury.

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: As an outcome-focused, electronic clinical quality measure (eCQM) which addresses a potential patient safety issue in acute care facilities, this measure addresses two high priority areas for future measure consideration for the Hospital Inpatient Quality Reporting (IQR) Program. This measure also relates to the goals for a focus on high-impact and outcome-based measures within CMS' Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Hospital-controlled factors that are associated with an increase in pressure ulcer risk include infrequent repositioning and number of days to bed change (<u>Tayyib</u>, <u>Coyer</u>, <u>and Lewis</u>, <u>2016</u>; <u>Bly et al.</u>, <u>2016</u>). It is important to address these factors because pressure injuries can lead to infection, osteomyelitis, anemia, sepsis in addition to depression, pain, and discomfort for patients (<u>Gunningberg et al.</u>, <u>2011</u>). <u>Guidelines</u> indicate that facilities can reduce the risk of pressure injuries through best practices and evidence-based interventions, including risk assessment, assessment of skin and tissue, preventive skin care, reducing progression through treatment of pressure injuries including nutrition, repositioning, and early mobilization.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: According to information provided by the measure developer, hospital-acquired pressure injuries are one of the most common patient harms. Specifically, the incidence of pressure injuries in hospitalized patients has been estimated at 5.4 per 10,000 patient-days and the rate of hospital-acquired pressure injuries is roughly 8.4 percent. More than half of reported pressure injuries in hospitals are Stage 2 or higher. The estimated annual number of inpatient hospitalizations of patients 18 years or older at risk is roughly 30,071,363.

Using electronic health record (EHR) data from 18 hospitals in 2020, the measure developer reported hospital level performance rates ranged from 0 percent to 2.02 percent, with an average score of 1.06 percent. While these rates are low, this is a patient safety event that should be avoided.

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

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Yes/No: Yes

Justification and Notes: Although this measure is similar to others used in different programs, because it is an eCQM it can be applied to a broader target population (not just Medicare beneficiaries). Additionally, because this measure is an eCQM, hospitals can receive reliable and timely pressure injury rates. This measure is the only electronic health record (EHR)-based measure intended for use in acute care hospitals related to pressure injuries.

A version of this measure was reviewed by the Measure Applications Partnership (MAP) for the Hospital IQR program and Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) (Medicare Promoting Interoperability Program) during the 2017-2018 prerulemaking cycle. The measure received a recommendation of "conditional support for rulemaking" pending NQF review and endorsement once the measure was fully tested. MAP supported the measure but had several concerns related to how the measure was specified. MAP also cautioned about potential bias against facilities that do not have the expertise needed to accurately stage pressure injuries (e.g., certified wound care nurses). MAP noted that risk adjustment may be necessary to ensure the measure does not disproportionately penalize facilities who may treat more complex patients (e.g., academic medical centers or safety net providers).

The MUC is also submitted for the Medicare Promoting Interoperability Program.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the measure developer, all data elements for this measure are in defined fields of electronic sources. To determine if critical data elements used in the measure are readily available in a structured format and routinely collected, the developer designed a web-based survey for 20 hospitals (three using Epic and 17 using Cerner) to complete. The developer states results were favorable among 18 out of the 20 hospitals; for two hospitals using Epic, staging information was only captured in unstructured notes. However, the developer notes that another hospital using Epic was able to capture staging information in structured fields, and therefore, does not anticipate a feasibility challenge. To determine if there was a burden to providers, the measure developer conducted a workflow analysis at the same 20 sites and found that provider workflow did not have to be modified to accommodate the measure (other than the one mentioned above).

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: This measure has been submitted to the consensus-based entity for endorsement but has not yet been reviewed (National Quality Forum (NQF) #3498e); however, it is fully developed and specified. The developer conducted signal-to-noise reliability testing and an intra-class correlation coefficient test, resulting in 0.97 and 0.916, respectively. The developer attested the results suggest the measure can distinguish performance rates between hospitals and that variability between hospitals appears to be due to real differences in quality of care.

The developer conducted empiric/convergent and face validity testing. For convergent validity testing, the developer compared the measure to 12 related quality measures using Spearman's rank correlation coefficient. Using Hospital Compare Data, the Spearman rank correlation between pilot sites' pressure

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injury scores and 12 quality measures provide evidence for moderate measure construct validity.

Overall, the developer attests the testing results indicate measure data element reliability and 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

Justification and Notes: The developer notes they did not identify unintended consequences during eCQM development or testing. However, the developer notes potential unintended consequences may include adverse outcomes among high-risk patients (respiratory complications, ventilator management difficulties, dislodged lines, etc.) because of increased turning to reduce the risk of pressure injuries. The developer states that CMS is committed to monitoring the eCQM's use and assessing potential unintended consequences over time.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group cited concerns regarding data collection and the potential for rural providers to perform poorly on the measure relative to other providers due to staffing shortages.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement by a consensus-based entity (CBE), with endorsement including a discussion of risk adjustment and stratification.

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

As an outcome-focused, electronic clinical quality measure (eCQM) which addresses a potential patient safety issue in acute care facilities, this measure addresses two high priority areas for future measure consideration for the Hospital Inpatient Quality Reporting (IQR) Program. This measure also relates to the goals for a focus on high-impact and outcome-based measures within CMS' Meaningful Measures Framework. Although this measure is similar to others used in different programs, because it is an eCQM it can be applied to a broader target population (not just Medicare beneficiaries). Additionally, because

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this measure is an eCQM, hospitals can receive reliable and timely pressure injury rates. This measure is the only electronic health record (EHR)-based measure intended for use in acute care hospitals related to pressure injuries. The MUC is also submitted for the Medicare Promoting Interoperability Program.

A version of this measure was reviewed by the Measure Applications Partnership (MAP) for the Hospital IQR program and Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) (Medicare Promoting Interoperability Program) during the 2017-2018 prerulemaking cycle. The measure received a recommendation of "conditional support for rulemaking" pending NQF review and endorsement once the measure was fully tested. MAP supported the measure but had several concerns related to how the measure was specified. MAP also cautioned about potential bias against facilities that do not have the expertise needed to accurately stage pressure injuries (e.g., certified wound care nurses). MAP noted that risk adjustment may be necessary to ensure the measure does not disproportionately penalize facilities who may treat more complex patients (e.g., academic medical centers or safety net providers).

MAP identified similar concerns to the ones identified during its 2017-2018 review. MAP noted the measure requires hospitals to have staff who are aware of pressure ulcers, are aware of their progression, and who have expertise staging ulcers. MAP also noted that certain factors may impact a hospital's score on the measure, including the hospital's number of complex patients, whether it is a safety net hospital, and the proportion of patients with food insecurity. However, other MAP members cautioned against risk adjusting for those factors, as patients in those groups are the ones that need assessment the most.

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

According to information provided by the measure developer, hospital-acquired pressure injuries are one of the most common patient harms. Specifically, the incidence of pressure injuries in hospitalized patients has been estimated at 5.4 per 10,000 patient-days and the rate of hospital-acquired pressure injuries is roughly 8.4 percent. More than half of reported pressure injuries in hospitals are Stage 2 or higher. The estimated annual number of inpatient hospitalizations of patients 18 years or older at risk is roughly 30,071,363.

Using EHR data from 18 hospitals in 2020, the measure developer reported hospital level performance rates ranged from 0 percent to 2.02 percent, with an average score of 1.06 percent. While these rates are low, this is a patient safety event that should be avoided.

Hospital-controlled factors that are associated with an increase in pressure ulcer risk include infrequent repositioning and number of days to bed change (<u>Tayyib</u>, <u>Coyer</u>, <u>and Lewis</u>, <u>2016</u>; <u>Bly et al.</u>, <u>2016</u>). It is important to address these factors because pressure injuries can lead to infection, osteomyelitis, anemia, sepsis in addition to depression, pain, and discomfort for patients (<u>Gunningberg et al.</u>, <u>2011</u>). <u>Guidelines</u> indicate that facilities can reduce the risk of pressure injuries through best practices and evidence-based interventions, including risk assessment, assessment of skin and tissue, preventive skin care, reducing progression through treatment of pressure injuries including nutrition, repositioning, and early mobilization.

Preliminary Analysis – MUC2022-064 Hospital Harm - Pressure Injury (Medicare Promoting Interoperability Program)

Program: Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs)

Measure Description:

The proportion of inpatient hospitalizations for patients 18 years of age or older at the start of the encounter, who suffer the harm of developing a new stage 2, stage 3, stage 4, deep tissue, or unstageable pressure injury.

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: As an outcome-focused, electronic clinical quality measure (eCQM) which addresses a potential patient safety issue in acute care facilities, this measure addresses two high priority areas for future measure consideration for the Hospital Inpatient Quality Reporting (IQR) Program. This measure also relates to the goals for a focus on high-impact and outcome-based measures within CMS' Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Hospital-controlled factors that are associated with an increase in pressure ulcer risk include infrequent repositioning and number of days to bed change (Tayyib, Coyer, and Lewis, 2016; Bly et al., 2016). It is important to address these factors because pressure injuries can lead to infection, osteomyelitis, anemia, sepsis in addition to depression, pain, and discomfort for patients (Gunningberg et al., 2011). Guidelines indicate that facilities can reduce the risk of pressure injuries through best practices and evidence-based interventions, including risk assessment, assessment of skin and tissue, preventive skin care, reducing progression through treatment of pressure injuries including nutrition, repositioning, and early mobilization.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: According to information provided by the measure developer, hospital-acquired pressure injuries are one of the most common patient harms. Specifically, the incidence of pressure injuries in hospitalized patients has been estimated at 5.4 per 10,000 patient-days and the rate of hospital-acquired pressure injuries is roughly 8.4 percent. More than half of reported pressure injuries in hospitals are Stage 2 or higher. The estimated annual number of inpatient hospitalizations of patients 18 years or older at risk is roughly 30,071,363.

Using electronic health record (EHR) data from 18 hospitals in 2020, the measure developer reported hospital level performance rates ranged from 0 percent to 2.02 percent, with an average score of 1.06 percent. While these rates are low, this is a patient safety event that should be avoided.

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

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measurement across programs?

Yes/No: Yes

Justification and Notes: Although this measure is similar to others used in different programs, because it is an eCQM it can be applied to a broader target population (not just Medicare beneficiaries). Additionally, because this measure is an eCQM, hospitals can receive reliable and timely pressure injury rates. This measure is the only electronic health record (EHR)-based measure intended for use in acute care hospitals related to pressure injuries.

A version of this measure was reviewed by the Measure Applications Partnership (MAP) for the Hospital Inpatient Quality Reporting (IQR) program and Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) (Medicare Promoting Interoperability Program) during the 2017-2018 pre-rulemaking cycle. The measure received a recommendation of "conditional support for rulemaking" pending NQF review and endorsement once the measure was fully tested. MAP supported the measure but had several concerns related to how the measure was specified. MAP also cautioned about potential bias against facilities that do not have the expertise needed to accurately stage pressure injuries (e.g., certified wound care nurses). MAP noted that risk adjustment may be necessary to ensure the measure does not disproportionately penalize facilities who may treat more complex patients (e.g., academic medical centers or safety net providers).

The MUC is also submitted for the Hospital IQR program.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: According to the measure developer, all data elements for this measure are in defined fields of electronic sources. To determine if critical data elements used in the measure are readily available in a structured format and routinely collected, the developer designed a web-based survey for 20 hospitals (three using Epic and 17 using Cerner) to complete. The developer states results were favorable among 18 out of the 20 hospitals; for two hospitals using Epic, staging information was only captured in unstructured notes. However, the developer notes that another hospital using Epic was able to capture staging information in structured fields, and therefore, does not anticipate a feasibility challenge. To determine if there was a burden to providers, the measure developer conducted a workflow analysis at the same 20 sites and found that provider workflow did not have to be modified to accommodate the measure (other than the one mentioned above).

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: This measure has been submitted to the consensus-based entity (CBE) for endorsement but has not yet been reviewed (National Quality Forum (NQF) #3498e); however, it is fully developed and specified. The developer conducted signal-to-noise reliability testing and an intra-class correlation coefficient test, resulting in 0.97 and 0.916, respectively. The developer attested the results suggest the measure can distinguish performance rates between hospitals and that variability between hospitals appears to be due to real differences in quality of care.

The developer conducted empiric/convergent and face validity testing. For convergent validity testing, the developer compared the measure to 12 related quality measures using Spearman's rank correlation

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coefficient. Using Hospital Compare Data, the Spearman rank correlation between pilot sites' pressure injury scores and 12 quality measures provide evidence for moderate measure construct validity.

Overall, the developer attests the testing results indicate strong measure data element reliability and 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

Justification and Notes: The developer notes they did not identify unintended consequences during eCQM development or testing. However, the developer notes potential unintended consequences may include adverse outcomes among high-risk patients (respiratory complications, ventilator management difficulties, dislodged lines, etc.) because of increased turning to reduce the risk of pressure injuries. The developer states that CMS is committed to monitoring the eCQM's use and assessing potential unintended consequences over time.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group cited concerns regarding data collection and the potential for rural providers to perform poorly on the measure relative to other providers due to staffing shortages.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group expressed no concerns regarding health equity and noted that the measure fills a quality gap.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on endorsement by a consensus-based entity (CBE), with endorsement including a discussion of risk adjustment and stratification.

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

As an outcome-focused, electronic clinical quality measure (eCQM) which addresses a potential patient safety issue in acute care facilities, this measure addresses two high priority areas for future measure consideration for the Hospital Inpatient Quality Reporting (IQR) Program. This measure also relates to the goals for a focus on high-impact and outcome-based measures within CMS' Meaningful Measures

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Framework. Although this measure is similar to others used in different programs, because it is an eCQM it can be applied to a broader target population (not just Medicare beneficiaries). Additionally, because this measure is an eCQM, hospitals can receive reliable and timely pressure injury rates. This measure is the only electronic health record (EHR)-based measure intended for use in acute care hospitals related to pressure injuries. The MUC is also submitted for the Hospital Inpatient Quality Reporting Program.

A version of this measure was reviewed by the Measure Applications Partnership (MAP) for the Hos pital IQR program and Medicare Promoting Interoperability Program for Eligible Hospitals (EHs) and Critical Access Hospitals (CAHs) (Medicare Promoting Interoperability Program) during the 2017-2018 prerulemaking cycle. The measure received a recommendation of "conditional support for rulemaking" pending NQF review and endorsement once the measure was fully tested. MAP supported the measure but had several concerns related to how the measure was specified. MAP also cautioned about potential bias against facilities that do not have the expertise needed to accurately stage pressure injuries (e.g., certified wound care nurses). MAP noted that risk adjustment may be necessary to ensure the measure does not disproportionately penalize facilities who may treat more complex patients (e.g., academic medical centers or safety net providers).

MAP identified similar concerns to the ones identified during its 2017-2018 review. MAP noted the measure requires hospitals to have staff who are aware of pressure ulcers, are aware of their progression, and who have expertise staging ulcers. MAP also noted that certain factors may impact a hospital's score on the measure, including the hospital's number of complex patients, whether it is a safety net hospital, and the proportion of patients with food insecurity. However, other MAP members cautioned against risk adjusting for those factors, as patients in those groups are the ones that need assessment the most.

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

According to information provided by the measure developer, hospital-acquired pressure injuries are one of the most common patient harms. Specifically, the incidence of pressure injuries in hospitalized patients has been estimated at 5.4 per 10,000 patient-days and the rate of hospital-acquired pressure injuries is roughly 8.4 percent. More than half of reported pressure injuries in hospitals are Stage 2 or higher. The estimated annual number of inpatient hospitalizations of patients 18 years or older at risk is roughly 30,071,363.

Using EHR data from 18 hospitals in 2020, the measure developer reported hospital level performance rates ranged from 0 percent to 2.02 percent, with an average score of 1.06 percent. While these rates are low, this is a patient safety event that should be avoided.

Hospital-controlled factors that are associated with an increase in pressure ulcer risk include infrequent repositioning and number of days to bed change (<u>Tayyib</u>, <u>Coyer</u>, <u>and Lewis</u>, <u>2016</u>; <u>Bly et al.</u>, <u>2016</u>). It is important to address these factors because pressure injuries can lead to infection, osteomyelitis, anemia, sepsis in addition to depression, pain, and discomfort for patients (<u>Gunningberg et al.</u>, <u>2011</u>). <u>Guidelines</u> indicate that facilities can reduce the risk of pressure injuries through best practices and evidence-based interventions, including risk assessment, assessment of skin and tissue, preventive skin care, reducing progression through treatment of pressure injuries including nutrition, repositioning, and early mobilization.

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (ASCQR)

Program: Ambulatory Surgical Center Quality Reporting Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062) in use within the Ambulatory Surgical Center Quality Reporting (ASCQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, ambulatory surgical centers (ASCs) reported a median coverage rate of booster/additional doses of 34 percent, with an interquartile range of 16.4 to 55.6 percent. This difference of 39.2 percentage points is indicative of a substantial quality challenge among ASC facilities.

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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: This revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among healthcare personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, 64 percent of ASC facilities already reported additional/booster coverage as of May 2022. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

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Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMITID 08062), which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have changed since the initial formulation of the measure, this revision includes reporting up-to-date vaccination (additional/booster dosing). This measure aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative. However, this MUC has not been fully tested or reviewed for endorsement by a consensus-based entity (CBE).

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

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

COVID-19 vaccination is highly effective against infection for healthcare workers and is associated with reduced patient infections and deaths. Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, ambulatory surgical centers (ASCs) reported a median coverage rate of booster/additional doses of 34 percent, with an interquartile range of 16.4 to 55.6 percent. This difference of 39.2 percentage points is indicative of a substantial quality challenge among ASC facilities.

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (Hospital IQR)

Program: Hospital Inpatient Quality Reporting Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062) in use within the Hospital Inpatient Quality Reporting (IQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those without high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, acute care hospitals reported a median coverage rate of booster/additional doses of 22.5 percent, with an interquartile range of 9.1 to 38.7 percent. This difference of 29.6

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percentage points is indicative of a substantial quality challenge among acute care hospitals.

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 revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among health care personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, the proportion of hospitals that already reported additional/booster coverage as of May 2022 was 74.6 percent. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

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Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMITID 08062) in use within the Hospital Inpatient Quality Reporting (IQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. This measure aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative. However, this MUC has not been fully tested or reviewed for endorsement by a consensus-based entity (CBE).

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

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

COVID-19 vaccination is highly effective against infection for healthcare workers and is associated with reduced patient infections and deaths. Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, acute care hospitals reported a median coverage rate of booster/additional doses of 22.5 percent, with an interquartile range of 9.1 percent to 38.7 percent. This difference of 29.6 percentage points is indicative of a substantial quality challenge among acute care hospitals.

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (Hospital OQR)

Program: Hospital Outpatient Quality Reporting Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current Coronavirus Disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062) in use within the Hospital Outpatient Reporting (OQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up to date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, ambulatory surgical centers (ASCs) reported a median coverage rate of booster/additional doses of 34 percent, with an interquartile range of 16.4 to 55.6 percent. This

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difference of 39.2 percentage points is indicative of a substantial quality challenge among ASC facilities, which may also extend to hospital outpatient departments (HOPDs).

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 revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among healthcare personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, 64 percent of ASC facilities and 74.6 percent of hospital facilities already reported additional/booster coverage as of May 2022. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

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Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMITID 08062) in use within the Hospital Outpatient Reporting (OQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have changed since the initial formulation of the measure, this revision includes reporting up-to-date vaccination (additional/booster dosing). This measure aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures 2.0 initiative. However, this MUC has not been fully tested or reviewed for endorsement by a consensus-based entity (CBE).

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

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

COVID-19 vaccination is highly effective against infection for healthcare workers and is associated with reduced patient infections and deaths. Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, ambulatory surgical centers (ASCs) reported a median coverage rate of booster/additional doses of 34 percent, with an interquartile range of 16.4 to 55.6 percent. This difference of 39.2 percentage points is indicative of a substantial quality challenge among ASC facilities, which may also extend to hospital outpatient departments (HOPDs).

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Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (HVBP)

Program: Hospital Value-Based Purchasing Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062), which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, acute care hospitals (ACH) reported a median coverage rate of additional dose/booster of 22.5 percent, with an interquartile range of 9.1 percent to 38.7 percent. This difference of 29.6 percentage points is indicative of a significant quality challenge among ACH facilities.

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 revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among health care personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, the proportion of ACH facilities that already reported booster coverage as of May 2022 was 74.6 percent. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

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Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

MAP did not vote on the measure for HVBP.

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

CMS does not intend to implement this measure in HVBP.

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

N/A

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (HACRP)

Program: Hospital-Acquired Condition Reduction Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062), which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, acute care hospitals (ACH) reported a median coverage rate of additional dose/booster of 22.5 percent, with an interquartile range of 9.1 percent to 38.7 percent. This difference of 29.6 percentage points is indicative of a significant quality challenge among ACH facilities.

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 revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among health care personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, the proportion of ACH facilities that already reported booster coverage as of May 2022 was 74.6 percent. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

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Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

MAP did not vote on the measure for HACRP.

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

CMS does not intend to implement this measure in HACRP.

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

N/A

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (IPFQR)

Program: Inpatient Psychiatric Facility Quality Reporting Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062) in use in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, inpatient psychiatric facilities (IPF) reported a median coverage rate of additional dose/booster of 19.1 percent, with an interquartile range of 8.7 percent to 37.9 percent. This difference of 29.2 percentage points is indicative of a significant quality challenge among IPFs.

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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: This revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among health care personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, the proportion of IPFs that already reported additional/booster coverage as of May 2022 was 74.3 percent. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

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Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMITID 08062) in use in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. This measure aligns with the preventive care domain of the CMS Meaningful Measures Framework. However, this MUC has not been fully tested or reviewed for endorsement by a consensus-based entity (CBE).

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

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

COVID-19 vaccination is highly effective against infection for healthcare workers and is associated with reduced patient infections and deaths. Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, inpatient psychiatric facilities (IPF) reported a median coverage rate of additional dose/booster of 19.1 percent, with an interquartile range of 8.7 percent to 37.9 percent. This difference of 29.2 percentage points is indicative of a significant quality challenge among IPFs.

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (PCHQRP)

Program: Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062) in use in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, acute care hospitals (ACHs) reported a median coverage rate of additional dose/booster of 22.5 percent, with an interquartile range of 9.1 percent to 38.7 percent. While the

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performance distribution for PPS-exempt cancer hospitals was not provided, this difference of 38.7 percentage points for ACHs could be indicative of a significant quality challenge among PPS-exempt cancer hospitals.

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 revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID-19 primary series vaccination among health care personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, the proportion of ACH facilities that already reported additional/booster coverage as of May 2022 was 74.6 percent. This high rate of reporting in ACHs suggests that the measure can be feasibly reported by hospitals.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Top of Document | COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (PCHQRP)

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Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062) in use in the Prospective Payment System-Exempt Cancer Hospital Quality Reporting (PCHQR) program, which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. This measure aligns with the preventive care domain of the CMS Meaningful Measures Framework. However, this MUC has not been fully tested or reviewed for endorsement by a consensus-based entity (CBE).

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

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

COVID-19 vaccination is highly effective against infection for healthcare workers and is associated with reduced patient infections and deaths. Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, acute care hospitals (ACHs) reported a median coverage rate of additional dose/booster of 22.5 percent, with an interquartile range of 9.1 percent to 38.7 percent. While the performance distribution for PPS-exempt cancer hospitals was not provided, this difference of 38.7 percentage points for ACHs could be indicative of a significant quality challenge among PPS-exempt cancer hospitals.

Preliminary Analysis – MUC2022-084 COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (ESRD QIP)

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

Measure Description:

Percentage of healthcare personnel who are considered up to date with recommended COVID-19 vaccines.

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: SARS-CoV-2 vaccination is a national healthcare priority. The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMIT ID 08062), which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. Up-to-date vaccination is defined as completing a COVID-19 vaccine primary series and receiving the most recent booster dose recommended by the <u>CDC</u>. This MUC aligns with the preventive care domain of the Centers for Medicare & Medicaid Services (CMS) Meaningful Measures Framework.

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

Yes/No: Yes

Justification and Notes: Healthcare practice requires close personal exposure to patients, contaminated environments, or infectious material from patients with SARS-CoV-2, putting healthcare workers at high risk of infection and contributing to further spread of COVID-19 (Nguyen et al., 2020). Observational data support the positive impact of COVID-19 vaccination and booster/additional dosing for healthcare personnel. COVID-19 vaccination is highly effective against infection for healthcare workers (Pilishvili et al., 2021) and is associated with reduced patient infections and deaths. In the presence of high community prevalence of COVID-19, nursing homes with low staff vaccination coverage had COVID-19 infections and death rates 132 percent and 195 percent higher, respectively, than those with high staff vaccination coverage (McGarry et al., 2022). Furthermore, additional/booster dosing is associated with a greater reduction in infections among both healthcare workers and patients relative to those who only received primary series vaccination (Prasad et al., 2022; Oster et al., 2022).

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, dialysis centers reported a median coverage rate of additional dose/booster of 14.7 percent, with an interquartile range of 5.4 percent to 31.3 percent. This difference of 25.9 percentage points is indicative of a significant quality challenge among dialysis centers.

<u>Top of Document</u> | COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (2022 revision) (ESRD QIP)

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 revision of the current measure captures up-to-date vaccination information in accordance with CDC recommendations updated since its initial development. The measure is under consideration for use in 11 CMS quality reporting programs. Additionally, the respecification of the target population is broader and simplified from seven categories of healthcare personnel to four.

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking" contingent on CMS bringing the measures back to MAP once the specifications were further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is expected to be reported to CDC's National Healthcare Safety Network (NHSN). CMS quality reporting programs already require facilities to report data on COVID -19 primary series vaccination among health care personnel. The developer notes that the feasibility of reporting additional/booster doses is evident by the proportion of facilities nationwide that have already reported this data to NHSN. Ahead of the August 2022 deadline, the proportion of dialysis centers that already reported additional/booster coverage as of May 2022 was 97.0 percent. This high rate of reporting suggests that the measure can be feasibly reported.

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: A prior version of this measure recently received consensus-based entity (CBE) endorsement (National Quality Forum (NQF) #3636). However, the MUC is not yet developed fully and is undergoing beta testing to assess the feasibility of collecting additional/booster vaccine dose data among healthcare personnel. In addition, the measure developer has not provided reliability or validity testing results for the MUC.

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: A prior version of the measure is currently in use in six CMS quality reporting programs. No unintended consequences to the patient were identified during implementation.

PAC/LTC Core Concept?

Yes/No: N/A

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Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually.

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group highlighted the importance of COVID measures.

Recommendation

Preliminary Analysis Recommendation:

Conditional Support for Rulemaking

Support of this measure is conditional on testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).

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

The measure under consideration (MUC) is a revision to the current coronavirus disease 19 (COVID-19) vaccination rate of healthcare personnel measure (CMITID 08062), which only captures primary series vaccination data. Because Centers for Disease Control and Prevention (CDC) recommendations for COVID-19 vaccination have been updated since the initial formulation of the measure, this revision includes reporting up-to-date vaccination. This measure aligns with the preventive care domain of the CMS Meaningful Measures Framework. However, this MUC has not been fully tested or reviewed for endorsement by a consensus-based entity (CBE).

This measure was reviewed by the Measure Applications Partnership (MAP) during the 2020-2021 prerulemaking cycle (MUC20-0044). MAP reviewed the measure for nine programs, giving it "conditional support for rulemaking," contingent on CMS bringing the measures back to MAP once the specifications are further refined, CMS considering an expedited process for the measures for both NQF and CMS, and CMS exploring the inclusion of pediatric hospitals within the COVID measures.

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

COVID-19 vaccination is highly effective against infection for healthcare workers and is associated with reduced patient infections and deaths. Existing healthcare personnel vaccination measures demonstrate variation in performance across facilities. Clinically significant differences in booster/additional dose vaccination coverage rates exist among facilities, indicating that revisions to the measure would be meaningful. For the first quarter of 2022, dialysis centers reported a median coverage rate of additional dose/booster of 14.7 percent, with an interquartile range of 5.4 percent to 31.3 percent. This difference of 25.9 percentage points is indicative of a significant quality challenge among dialysis centers.

Preliminary Analysis – MUC2022-125 Gains in Patient Activation Measure (PAM) Scores at 12 Months

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

Measure Description:

The Patient Activation Measure (PAM) (Registered Trademark) is a 10- or 13- item questionnaire that assesses an individual's knowledge, skills and confidence for managing their health and health care. The measure assesses individuals on a 0-100 scale that converts to one of four levels of activation, from low (1) to high (4). The PAM performance measure (PAM-PM) is the change in score on the PAM from baseline to follow-up measurement. A positive change would mean the patient is gaining in their ability to manage their health. The measure is not disease specific but has been successfully used with a wide variety of chronic conditions, as well as with people with no medical diagnosis.

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 patient-reported outcome performance measure (PRO-PM) addresses the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) priorities of Outcomes and Patient-and-Caregiver-Centered Experience of Care, specifically, patient-reported outcomes. As a PRO-PM, it contributes to patient-centered care and focuses on the patient voice. The Patient Activation Measure (PAM) survey collects information directly from patients regarding their knowledge, skill, and confidence for managing their health and healthcare.

It is difficult to assess what rate from the measure numerator will be reported by clinicians participating in the ESRD QIP. The developer mentions several options: the aggregate of differences between Baseline PAM score and a second score (a continuous variable measure), the proportion of eligible patients who achieved a net increase in PAM score of at least 3 points in a 6-12 month period (passing), and the proportion of eligible patients who achieved a net increase in PAM score of at least 6 points in a 6-12 month period (excellent). Clarity around the measure rate is requested in order to fully understand how the measure would be implemented in the ESRD QIP.

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

Yes/No: Yes

Justification and Notes: The developer's submission for the consensus-based entity (CBE) endorsement in 2015 describes the logic model for how provider interventions can improve this outcome. Specifically, accessing patient activation will drive targeted coaching and support by the clinical team, which in turn can increase patient activation and improve health outcomes. Overall, provider or dialysis facility interventions that tailor support to the person's level of activation, build skills and confidence, use peer support, and change the social environment have a positive impact on this activation measure as well as other outcomes (Hibbard et a., 2013).

The developer shared in their 2015 submission to the CBE that over 240 articles have been published regarding the Patient Activation Measure (PAM). Of these studies, at least 85 percent show a statistically significant relationship between PAM scores and positive health actions, including getting preventive screening tests, immunizations, and health checkups. Many of these studies indicate that the higher the

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PAM score, the better health and clinical outcomes for the patient.

The developer also provided data from dialysis facilities demonstrating that patient support/coaching was associated with a change in PAM score and PAM level over time. However, this data is unpublished and was not analyzed for statistical significance.

Does the measure address a quality challenge?

Yes/No: Yes

Justification and Notes: In the developer's submission for the CBE endorsement in 2015, they demonstrated a mean performance of 57.4 to 68.2 depending on the study. The standard deviation was 9.9 to 13.3 for U.S.-based studies. While these data demonstrate significant variation and gaps in care that are indicative of a quality challenge, it is unclear if this range of performance represents performance at the dialysis-facility level.

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 to two measures used in post-acute care/long-term care settings. These measures also estimate members' ability to self-manage their conditions and effectively participate in care activities. The measure under consideration (MUC) differs from the other measures in that it is broadly applicable to various patients with different diseases and needs. It is also proposed for different programs (the Merit-based Incentive Payment System (MIPS) and ESRD QIP). The measure is in use in two Center for Medicare & Medicaid Innovation (CMMI) programs: Kidney Care Choices (2022) and Maternal Opioid Misuse (2021-2022).

Can the measure be feasibly reported?

Yes/No: Yes

Justification and Notes: The measure is fully developed and operationalized electronically. Data can be collected at the point of care (in-person), via IVR, through the patient portal, or via the mail. Most electronic health records (EHRs) can accommodate PAM data, when needed. PAM questions and scoring have been integrated into various electronic medical records (e.g., Epic, eClinicalWorks), and care management software (e.g., CaseTrakker, McKesson CCR/Vitals). As of September 2022, PAM scores have been collected from 71,790 people across 67 practices which demonstrates that feasibility can be achieved by collecting baseline data and following up as necessary. While the measure is being used in the CMII Kidney Care Choices program, it is unclear if dialysis facilities outside of demonstrations would find the measure feasible to implement.

The developer states the survey instrument used to collect the data informing the proposed measure will be provided to the Centers for Medicare & Medicaid Services (CMS), and will be publicly available at no charge.

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 developed, endorsed by a consensus-based entity (CBE)

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(National Quality Forum (NQF) #2483), and measure testing has demonstrated reliability and validity. The measure was scored for reliability through Cronbach's alpha analysis. In a study conducted with patients who have chronic kidney disease (CKD), data were assessed through mean, item response, missing values, floor and ceiling effects, internal consistency (Cronbach's alpha and average interitem correlation), and item-rest correlations. The item response was high, with a small number of missing values (<1 percent). The floor effect was small (range 1-5 percent), but the ceiling effect was above 15 percent for nine items (range 15-38 percent). The Patient Activation Measure demonstrated good internal consistency overall (Cronbach α =0.925, and average interitem correlation 0.502). The authors concluded that the 13-item Patient Activation Measure appears to be a suitably reliable and valid instrument for assessing patient activation in ESRD.

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: Feedback from end users has not identified any negative unintended consequences to patients or any unreasonable implementation issues that outweigh the benefits of the measure.

PAC/LTC Core Concept?

Yes/No: N/A

Impact Act Domain

Yes/No: N/A

Hospice High-Priority Areas

Yes/No: N/A

MAP Rural Health Advisory Group Input:

The Rural Health Advisory Group shared this measure could have unintended consequences for the rural health providers due to limited access to health care resources (i.e., patients' attitudes, motivators, and behaviors with regard to seeking health care).

MAP Health Equity Advisory Group Input:

The Health Equity Advisory Group discussed that this measure can advance health equity and improve patient engagement in their health. The Health Equity Advisory Group also shared that safety net providers may experience challenges making gains in the measure.

Recommendation

Preliminary Analysis Recommendation:

Support for Rulemaking

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

This measure addresses the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) priorities of Outcomes and Patient-and-Caregiver-Centered Experience of Care, specifically, patient-reported

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outcomes. The Patient Activation Measure (PAM) survey collects information directly from patients regarding their knowledge, skill, and confidence for managing their health and healthcare. It is not disease specific and has been used with a wide variety of chronic conditions, as well as with people with no medical diagnosis. As a PRO-PM, it contributes to patient-centered care and focuses on the patient voice.

A MAP member requested that the measure be specifically reviewed by the National Quality Forum's Renal Standing Committee. Another MAP member expressed concern that the PAM is a universal tool and not built around a specific condition. Lastly, a MAP member requested review of data from the measure's use in a demonstration project before its implementation in the ESRD QIP.

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

This PRO-PM provides a standardized method for dialysis facilities to assess patient activation through the continuum of care. The developer's submission for the consensus-based entity (CBE) endorsement in 2015 highlighted the impact of targeted interventions on increased patient engagement, activation and improved outcomes. The PAM score (and changes in PAM scores) are predictive of health behavior, clinical outcomes, and costs, and can indicate the degree to which these interventions are occurring. The underlying assumption is patients that receive high-quality care, including interventions such as coaching and support, will increase their activation (ability to manage their disease), and improve their ability to self-manage over time. The measure is endorsed by the consensus-based entity (National Quality Forum (NQF) #2483). The developer states the survey instrument used to collect the data informing the proposed measure will be provided to the Centers for Medicare & Medicaid Services (CMS), and will be publicly available at no charge.