NATIONAL QUALITY FORUM
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# Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care Workgroup: 2021-2022 Cycle Preliminary Analyses

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## Inpatient Rehabilitation Facility Quality Reporting Program

MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

# Section 1: Measure Information

*Measure Specifications and Endorsement Status*

**Program**
Inpatient Rehabilitation Facility Quality Reporting Program, Long-Term Care Hospital Quality Reporting Program, Skilled Nursing Facility Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Hospital Inpatient Quality Reporting Program, Medicare Promoting Interoperability Program for Hospitals, Prospective Payment System (PPS)-Exempt Cancer Hospitals Quality Reporting Program

**Workgroup**
PAC/LTC

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

**Numerator**
Healthcare-Associated Clostridioides difficile Infection (HA-CDI):

Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.

HA-CDI 1: must meet BOTH A & B.

A) Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.

B) Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

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

A) Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.

B) Administration of oral or intravenous metronidazole within the window period extending 2

calendar days before and 2 calendar days after the date of stool specimen collection in part A.

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

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

**Denominator Exclusions**
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count.

Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

**Denominator Exceptions**
Under investigation, subject to change.

**State of development**
Specification

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

**What is the target population of the measure?**
All Payer

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

**Measure Type**
Outcome; Outcome

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

**If Other, Please Specify**
N/A

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

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

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

1. Microbiology records of stool tests for C. difficile, typically from an EHR laboratory information

system.
2. Medication administration records (eg. antimicrobial administration), from EHR.
3. Administration records, non-claims (eg. date of admission, discharge, patient location).

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

**At what level of analysis was the measure tested?**
Facility

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

**What one healthcare domain applies to this measure?**
Safety

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

**CMIT ID**
N/A

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Never Submitted

**NQF ID Number**
N/A

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

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

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

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

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

**Submitter Comments**
N/A

*Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

*Measure Use in CMS Programs*

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

**Previous Measure Information**
N/A

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

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

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

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

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

**How will this measure be distinguished from other similar and/or competing measures?**
The current NHSN measure is based on laboratory results, and C. difficile is typically diagnosed using non-culture based diagnostic tests which have wide variation in sensitivity and in rates of false positives.

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

**How will this measure add value to the CMS program?**

This new measure increases the clinical validity of original measure, and therefore more accurately reflect the presence of clinical infection and quality measurement.

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

N/A

## *Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**

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

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

References

(1) Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI

(2) Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458

(3) Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf

(4) Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN

(5) McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

**Evidence that the measure can be operationalized**

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

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

Other: CDC NHSN submission to CMS

**Feasibility of Data Elements**

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

**Evidence of Performance Gap**

Analysis forthcoming.

**Unintended Consequences**

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

**Outline the clinical guidelines supporting this measure**

N/A

**Were the guidelines graded?**

N/A

**If yes, who graded the guidelines?**

N/A

**If yes, what was the grade?**

N/A

**Estimated Impact of the Measure: Estimate of Annual Denominator Size**

Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

**Estimate of Annual Improvement in Measure Score**

To be determined.

**Type of Evidence to Support the Measure**
Empirical data

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

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

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

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

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

**Year of Cost Literature Cited**
October 2015 through June 2019.

*Patient and Provider Perspective*

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

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

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

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

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

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

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

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

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

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

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

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

**Total Number of Clinicians/Providers Consulted**
N/A

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

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

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

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

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

**Does the measure require manual abstraction?**
No

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

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

*Measure Testing Details*

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

**Type of Reliability Testing**
Measure Score Reliability

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

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

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

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

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

**Type of Validity Testing**
N/A

**Measure Score Validity**
N/A

**Validity Testing: Type of Validity Testing Analysis**
Construct Validity

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

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

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

**Measure performance – Type of Score**
Ratio

**Measure Performance Score Interpretation**
Lower score is better

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

Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HA-CDI events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect

standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

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

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

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

**Benchmark, if applicable**

See methods above for calculation of SIR and ARM.

## *Measure Contact Information*

**Measure Steward**

Centers for Disease Control and Prevention

**Measure Steward Contact Information**

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**Long-Term Measure Steward**
Centers for Disease Control and Prevention

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**Primary Submitter Contact Information**
N/A

**Secondary Submitter Contact Information**
N/A

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

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

**Justification and Notes:** The Measure Under Consideration calculates the observed number of Healthcare-Associated Clostridioides difficile Infections (HA-CDIs) at a health care facility, divided by the number of infections expected based on facility characteristics. This measure would update a very similar measure currently included in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP), NQF #1717, by only counting cases where there was evidence of both a positive test and treatment. Measuring healthcare-associated infections remains a high priority for the IRF QRP, and Patient Safety is a Meaningful Measures 2.0 area.

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

**Justification and Notes:** After several years of implementation of HA-CDI quality measures, a 48 percent

decrease in reported HA-CDIs within Inpatient Rehabilitation Facilities (IRFs) was observed from 2015-2020 (Centers for Disease Control and Prevention, 2021). This indicates IRFs have successfully implemented initiatives, such as CDC's guidelines for hand hygiene, that are reducing infection rates (2002). This measure is intended to capture HA-CDI infections more precisely than the existing measure by only counting those infections among inpatients that both a position laboratory test and evidence of an antimicrobial agent administered to the patient two days before or after the positive test result.

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

**Justification and Notes:** HA-CDIs are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDIs were reported to the CDC (2021). CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures (2019). According to National and State Healthcare-Associated Infections reports, in 2020 the 20$^{th}$ percentile of performance for IRFs was .00 infections observed/expected, compared to an 80$^{th}$ percentile performance of .878 infections observed/expected, indicating a substantial range in performance (CDC, 2021).

**Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?**
**Yes/No:** Yes

**Justification and Notes:** This measure would replace a similar, existing measure of HA-CDI infections observed/expected already included in the IRF QRP. Versions of the same HA-CDI monitoring measure are also currently in use for quality reporting programs for acute care hospitals and IRFs.

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

**Justification and Notes:** All data elements required to calculate the measure are available in defined fields in electronic data. The HA-CDI measure currently implemented in the program has been successfully submitted by hundreds of long-term care hospitals for several years

**Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?**
**Yes/No:** Yes

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

**If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?**
**Yes/No:** N/A

**Justification and Notes:** This measure is not in current use. The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test for CDI AND a treatment administered. This update is intended to

mitigate instances where a facility or provider might be incentivized not to test for a suspected HA-CDI.

### PAC/LTC Core Concept?

**Yes/No:** Yes

**Justification:** This measure meets one of the 13 core concepts, infection rates, which specifically indicates HAIs on the core concept list.

### Impact Act Domain

**Yes/No:** No

**Justification:** This measure does not meet one of the 8 Impact Act domains.

### Hospice High Priority Areas

**Yes/No:** N/A

**Justification:** N/A

### MAP Rural Health Advisory Group Input:

**Relative priority/utility:**

- HAIs are extremely important to monitor

**Data collection issues:**

- None

**Calculation issues:**

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

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 4.0
1 – 0 votes
2 – 0 votes
3 – 1 vote
4 – 9 votes
5 – 1 votes

### MAP Health Equity Advisory Group Input:

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

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 3.5
1 – 0 votes

2 – 2 votes
3 – 6 votes
4 – 8 votes
5 – 1 vote

*Recommendation*

**Preliminary Analysis Recommendation:**

Conditional Support for Rulemaking, pending NQF endorsement and successful testing of reliability and validity.

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

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

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

A HA-CDI infection has serious potential consequences for patients, including death. Nearly 114,000 HA-CDI were reported to the CDC in 2020. The performance of IRFs on the existing HA-CDI measure shows considerable variation in performance: the 20th percentile of performance for IRFs was .00 infections observed/expected, compared to an 80th percentile performance of .878 infections observed/expected. Nevertheless, this performance has improved by 48 percent over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines.

The conditions for Support for Rulemaking are for the measure to be submitted to NQF for endorsement, as well as for reliability and validity testing to be successfully completed.

## Section 3: Public Comments

**Encompass Health Corporation**

Comment The proposed measure is vague regarding the 'specific antimicrobial agent or other therapy' and how that is being incorporated into the measure. It could either be interpreted as refining the existing measure definition (only focused on clinical significant C Diff infections) or as expanding the existing definition to try to catch events that are being 'missed'. If the proposal is focusing on just clinically significant infections then it makes sense and shouldn't cause issues. If the proposal is

incorporating drug orders to attempt to prevent manipulation of infection rates then more information is needed and it could be confusing for hospitals.

“this new NHSN measure includes not only the lab test for C. difficile but also the use of a specific antimicrobial agent or other therapy as part of the definition. (The MUC list does not specify the specific antimicrobial agents.) In this approach, use of therapy acts as a proxy for a clinically significant infection – and is especially possible because of the specific therapies used for infections due to C. difficile.”

A. If this means that both the positive test and the drug order are needed for reporting then the measure is focusing on clinical significant C Diff infections, not reporting colonization, etc.. This would likely decrease the number of events reported by making the requirements more stringent. This would narrow the measure and reflect a more clinically meaningful rate of infection. However, the rates in IRF are already low and the burden may outweigh the benefit of reporting.

B. If this means either the positive test or the drug order are needed for reporting then this could cause confusion as some drugs used to treat C Diff are also used for other purposes (vancomycin, fidaxomicin, etc.). This could cause some events to be reported that aren’t needed, over-estimating the number of events. If the ‘specific antimicrobial agent’ is limited to Bezlotoxumab or some other drug that is more specific to C Diff that may make more sense.

**Federation of American Hospitals**

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

### American Medical Rehabilitation Providers Association (AMRPA)

Dear Measure Applications Partnership,

The American Medical Rehabilitation Providers Association (AMRPA) appreciates the opportunity to submit comments in response to the Measure Under Consideration (MUC) MUC21-098 "National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure" for inclusion in the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP). AMRPA is the national trade association representing more than 650 freestanding inpatient rehabilitation facilities and rehabilitation units of acute-care general hospitals (referred to by policymakers as inpatient rehabilitation "facilities," or IRFs). The vast majority of our members are Medicare participating providers. In 2019, IRFs served 363,000 Medicare beneficiaries with more than 409,000 IRF stays.

AMRPA recognizes the importance of including diverse and well-designed quality measures that meaningfully distinguish high-quality care in the IRF QRP. We also recognize that healthcare-acquired c. diff infections (HA-CDI) can have catastrophic consequences for patients, or at minimum, affect a patient's ability to participate in their rehabilitation program. However, AMRPA believes this measure does not add value to the IRF QRP. We therefore urge NQF to "rescind its conditional support for rulemaking" recommendation on this measure for the IRF QRP prior to issuing its final report to the Centers for Medicare and Medicaid Services (CMS).

While IRFs do encounter HA-CDI, albeit at a very low rate – 1,433 observed hospital-onset events out of 496,508 (<1%) admissions in 2020 - IRFs are limited in their ability to decrease infection incidence due to the rate of antibiotic prescribing in acute-care hospitals. A leading cause of HA-CDI is a result of overuse of antibiotics. When a patient is prescribed an antibiotic regimen by a referring hospital, the downstream IRFs are limited in their ability to address the underlying cause of the HA-CDI. In other words, patients that ultimately test positive for HA-CDI were often prescribed antibiotics in an acute-care hospital several days prior to the symptom onset within the IRF. The purpose of the IRF QRP is to distinguish high-quality care across the IRF field, and assist patients, caregivers and discharge planners in determining appropriate discharge locations. With the limited incidence of HA-CDI within IRFs, coupled with the limitations in controlling new incidents, this is not an appropriate indicator for measuring IRF quality, and therefore is limited in its ability in assisting health care consumers.

Additionally, AMRPA continues to have concerns surrounding provider burden related to quality measure collection and reporting. In addition to ensuring measures within the IRF QRP accurately and adequately measure quality of care within IRFs, it is crucial that the burden of collecting a measure does not outweigh any potential benefits – which is in line with CMS' Meaningful Measures initiative. As acknowledged by some Post-Acute/Long-Term Care Workgroup members during the December 16, 2021 meeting, many rehabilitation hospitals are still manually reporting many of the IRF QRP measures – an issue confirmed by many AMRPA member hospitals. AMRPA believes provider burden necessary for collecting and reporting HA-CDI combined with the limited incidence within IRFs warrants this measure's exclusion from the IRF QRP. We therefore urge NQF to rescind its "conditional support for rulemaking" recommendation for MUC21-098 "National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure," and instead recommend CMS utilize more relevant measures in the IRF QRP.

Lastly, AMRPA appreciates the opportunity to comment on such an important aspect of the IRF QRP. From an operational standpoint and given the critical importance of quality measures to the rehabilitation field, we urge NQF to lengthen the comment period for MUCs going forward. Increasing the comment period duration would grant stakeholders the ability to give the MUCs more thoughtful consideration and provide more robust comments to NQF in advance of the workgroup meetings.

***

AMRPA thanks the National Quality Forum for allowing us the opportunity to provide feedback. AMRPA stands ready to work with NQF to help ensure meaningful and appropriate quality measures continue to be included in the IRF QRP. Should you wish to discuss these comments further, please contact Kate Beller, AMRPA Executive Vice President for Government Relations and Policy Development (kbeller@amrpa.org / 202.207.1132) or Remy Kerr, AMRPA Director of Health Policy and Quality (rkerr@amrpa.org / (202.207.1126).

Sincerely,

Anthony Cuzzola

Chair, AMRPA Board of Directors

Vice President/Administrator, JFK Johnson Rehabilitation Institute, Hackensack Meridian Health

Suzanne Kauserud, FACHE, MBA, PT

Chair, AMRPA Quality of Care Committee

Member, AMRPA Board of Directors

Vice President, Atrium Health

1. Inpatient rehabilitation facilities (IRFs) – both freestanding and units located within acute-care hospitals – are fully licensed hospitals that must meet Medicare Hospital Conditions of Participation (COPs) and provide hospital-level care to high acuity patients. IRFs' physician-led care, competencies, equipment and infection control protocols are just some of the features that distinguish the hospital-level care provided by IRFs from most other PAC providers.

2. MEDICARE PAYMENT ADVISORY COMM., REPORT TO THE CONGRESS, MEDICARE PAYMENT POLICY (2021).

3. National Healthcare Safety Network (NHSN), 2020 National and State HAI Progress Report SIR Data – Inpatient Rehabilitation Facilities, Accessed January 8, 2022.

4. Sophia V Kazakova, James Baggs, L Clifford McDonald, Sarah H Yi, Kelly M Hatfield, Alice Guh, Sujan C Reddy, John A Jernigan, Association Between Antibiotic Use and Hospital-onset Clostridioides difficile Infection in US Acute Care Hospitals, 2006–2012: An Ecologic Analysis, Clinical Infectious Diseases, Volume 70, Issue 1, 1 January 2020, Pages 11–18, https://doi.org/10.1093/cid/ciz169

## Long-Term Care (LTC) Hospital Quality Reporting Program

MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

# Section 1: Measure Information

*Measure Specifications and Endorsement Status*

**Program**

Long-Term Care (LTC) Hospital Quality Reporting Program, Inpatient Rehabilitation Facility Quality Reporting Program, Skilled Nursing Facility Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Hospital Inpatient Quality Reporting Program, Medicare Promoting Interoperability Program for Hospitals, Prospective Payment System (PPS)-Exempt Cancer Hospitals Quality Reporting Program

**Workgroup**

PAC/LTC

**Measure Description**

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

**Numerator**

Healthcare-Associated Clostridioides difficile Infection (HA-CDI):

Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.

HA-CDI 1: must meet BOTH A & B.

A) Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.

B) Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

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

A) Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.

B) Administration of oral or intravenous metronidazole within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

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

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

**Denominator Exclusions**
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count.

Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

**Denominator Exceptions**
Under investigation, subject to change.

**State of development**
Specification

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

**What is the target population of the measure?**
All Payer

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

**Measure Type**
Outcome;Outcome

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

**If Other, Please Specify**
N/A

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

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

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

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

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

**At what level of analysis was the measure tested?**
Facility

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

**What one healthcare domain applies to this measure?**
Safety

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

**CMIT ID**
N/A

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Never Submitted

**NQF ID Number**
N/A

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

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

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

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

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

**Submitter Comments**
N/A

*Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

*Measure Use in CMS Programs*

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

**Previous Measure Information**
N/A

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

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

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

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

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

Clostridium difficile Infection (CDI) Outcome Measure

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

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

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

## *Measure Evidence*

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

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

**References**

(1) Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI

(2) Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458

(3) Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf

(4) Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN

(5) McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

**Evidence that the measure can be operationalized**

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

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

Other: CDC NHSN submission to CMS

**Feasibility of Data Elements**

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

**Evidence of Performance Gap**

Analysis forthcoming.

**Unintended Consequences**

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

**Outline the clinical guidelines supporting this measure**

N/A

**Were the guidelines graded?**

N/A

**If yes, who graded the guidelines?**

N/A

**If yes, what was the grade?**

N/A

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

**Estimate of Annual Improvement in Measure Score**
To be determined.

**Type of Evidence to Support the Measure**
Empirical data

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

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

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

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

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

**Year of Cost Literature Cited**
October 2015 through June 2019.

*Patient and Provider Perspective*

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

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

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

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

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

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

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

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

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

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

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

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

**Total Number of Clinicians/Providers Consulted**
N/A

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

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

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

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

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

**Does the measure require manual abstraction?**
No

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

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

*Measure Testing Details*

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

**Type of Reliability Testing**
Measure Score Reliability

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

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

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

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

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

**Type of Validity Testing**
N/A

**Measure Score Validity**
N/A

**Validity Testing: Type of Validity Testing Analysis**
Construct Validity

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

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

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

**Measure performance – Type of Score**
Ratio

**Measure Performance Score Interpretation**
Lower score is better

**Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have**
HA-CDI performance will be measured using methods already in use for other CDC NHSN measures: the

Standardized Infection Ratio (SIR), and the Adjusted Ranking Metric (ARM).

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

1) Identify the number of unique HA-CDI events for a given time period by adding the total number of observed events across the facility.

2) Calculate the number of expected HA-CDI events for the facility using the negative binomial regression model.

3) Divide the number of observed HA-CDI events (1 above) by the number of expected HA-CDI events (2 above) to obtain the SIR.

4) Perform a mid-P Exact Test to compare the SIR obtained in 3 above to the nominal value of 1. P-value and 95% confidence intervals will be calculated, which can be used to assess statistical significance of SIR.

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

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

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

**Benchmark, if applicable**

See methods above for calculation of SIR and ARM.

*Measure Contact Information*

**Measure Steward**
Centers for Disease Control and Prevention

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

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

**Primary Submitter Contact Information**
N/A

**Secondary Submitter Contact Information**
N/A

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

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

**Yes/No:** Yes

**Justification and Notes:** The Measure Under Consideration calculates the observed number of Healthcare-Associated Clostridioides difficile Infections (HA-CDI) at a health care facility, divided by the number of infections expected based on facility characteristics. This measure would update a very similar measure currently included in the Long-Term Care Hospital Quality Reporting Program (LTCH

QRP), NQF #1717, by only counting cases where there was evidence of both a positive test and treatment. Measuring healthcare-associated infections remains a high priority for the LTCH program, and Patient Safety is a Meaningful Measures 2.0 area.

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

**Justification and Notes:** After several years of implementation of HA-CDI quality measures, a 60 percent decrease in reported HA-CDI was observed in Long-Term Care Acute Hospitals from 2015-2020. This indicates hospitals have successfully implemented initiatives, such as CDC guidelines for hand hygiene, that are reducing infection rates. This measure is intended to capture HA-CDI infections more precisely than the existing measure by only counting those infections among inpatients that both a position laboratory test and evidence of an antimicrobial agent administered to the patient two days before or after the positive test result.

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

**Justification and Notes:** HA-CDI infections are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDI infections were reported to the CDC. CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures. According to NHSN reports, in 2020 the 20$^{th}$ percentile of performance for long-term care hospitals was .094 infections observed/expected, compared to an 80$^{th}$ percentile performance of .687 infections observed/expected, indicating a substantial range in performance.

**Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?**
**Yes/No:** Yes

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

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

**Justification and Notes:** All data elements required to calculate the measure are available in defined fields in electronic data. The HA-CDI measure currently implemented in the program has been successfully submitted by hundreds of long-term care hospitals for several years.

**Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?**
**Yes/No:** No.

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

validity testing has not been finalized.

**If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?**
**Yes/No:** No

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

**PAC/LTC Core Concept?**
**Yes/No:** Yes

**Justification:** This measure meets one of the 13 core concepts, infection rates, which specifically indicates HAIs on the core concept list.

**Impact Act Domain**
**Yes/No:** Yes

**Justification:** This measure does not meet one of the 8 Impact Act domains.

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

**Justification:** N/A

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

- HAIs are extremely important to monitor

**Data collection issues:**

- None

**Calculation issues:**

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

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 4.0
1 – 0 votes
2 – 0 votes
3 – 1 votes

4 – 9 votes
5 – 1 votes

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

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 3.5
1 - 0 votes
2 - 2 votes
3 - 5 votes
4 - 9 votes
5 - 1 vote

## *Recommendation*

**Preliminary Analysis Recommendation:**

Conditional Support for Rulemaking, pending NQF endorsement and successful testing of reliability and validity.

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

This Measure Under Consideration would modify the existing HA-CDI surveillance measure in the LTCH quality reporting program, by only counting cases where there was evidence of both a positive test and treatment. This may mitigate potential unintended consequences from the current measure's design, counting a case based on a positive test only, which may have led to a historical under-counting of observed HA-CDI. This updated measure is consistent with the program's priority to measure healthcare associated infections, and the Patient Safety Meaningful Measures 2.0 area.

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

A HA-CDI infection has serious potential consequences for patients, including death. Nearly 114,000 HA-CDI were reported to the CDC in 2020. The performance of long-term care hospitals on the existing HA-CDI measure shows considerable variation in performance: the 20th percentile of performance for long-term care hospitals was .094 infections observed/expected, compared to an 80th percentile performance of .687 infections observed/expected. Nevertheless, this performance has improved by 60 percent over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines.

The conditions for Support for Rulemaking are for the measure to be submitted to NQF for endorsement, as well as for reliability and validity testing to be successfully completed.

## Section 3: Public Comments

### Federation of American Hospitals

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

## Skilled Nursing Facility Quality Reporting Program

MUC2021-123 Influenza Vaccination Coverage among Healthcare Personnel

# Section 1: Measure Information

*Measure Specifications and Endorsement Status*

**Program**
Skilled Nursing Facility Quality Reporting Program

**Workgroup**
PAC/LTC

**Measure Description**
Percentage of healthcare personnel (HCP) who receive the influenza vaccination.

**Numerator**
HCP in the denominator population who during the time from October 1 (or when the vaccine became available) through March 31 of the following year:

(a) received an influenza vaccination administered at the healthcare facility, or reported in writing (paper or electronic) or provided documentation that influenza vaccination was received elsewhere; or

(b) were determined to have a medical contraindication/condition of severe allergic reaction to eggs or to other component(s) of the vaccine, or history of Guillain-Barré Syndrome within 6 weeks after a previous influenza vaccination; or

(c) declined influenza vaccination

Numerators are to be calculated separately for each of the above groups.

**Numerator Exceptions**
N/A

**Denominator**
Number of HCP who are working in the healthcare facility for at least 1 working day between October 1 and March 31 of the following year, regardless of clinical responsibility or patient contact.

Denominators are to be calculated separately for:

(a) Employees: all persons who receive a direct paycheck from the reporting facility (i.e., on the facility's payroll).

(b) Licensed independent practitioners: include physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility who do not receive a direct paycheck from the reporting facility.

(c) Adult students/trainees and volunteers: include all students/trainees and volunteers aged 18 or over who do not receive a direct paycheck from the reporting facility.

**Denominator Exclusions**
N/A

**Denominator Exceptions**
N/A

**State of development**
Fully Developed

**State of Development Details**
Testing description: Reliability was assessed by comparing agreement between facility staff and project staff on the classification of HCP numerator (vaccinated at facility, vaccinated elsewhere, contraindicated, declined) and denominator (employees, credentialed nonemployees, other nonemployees) categories. To assess validity, facility staff completed a series of case studies to evaluate how closely classification of HCP groups aligned with the measure's specifications. In a modified Delphi process, experts rated face validity of the proposed measure elements on a Likert-type scale.

Setting: 96 acute care hospitals, long-term care facilities, ambulatory surgery centers, physician practices, and dialysis centers from 3 U.S. jurisdictions.

Results: Percent agreement was high for HCP vaccinated at the facility (99%) and elsewhere (95%) and was lower for HCP who declined vaccination (64%) or were medically contraindicated (64%). While agreement was high (more than 90%) for all denominator categories, many facilities' staff excluded nonemployees for whom numerator and denominator status was difficult to determine. Validity was lowest for credentialed and other nonemployees.

**What is the target population of the measure?**
Healthcare Personnel

**Areas of specialty the measure is aimed to, or specialties that are most likely to report this measure**
Other: All areas of specialty that work in acute care hospitals or other healthcare facilities that are in the measure scope.

**Measure Type**
Process

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

**If Other, Please Specify**
N/A

**What data sources are used for the measure?**
Electronic Clinical Data (non-EHR); Paper Medical Records

**If applicable, specify the data source**
N/A

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

**At what level of analysis was the measure tested?**
Facility

**In which setting was this measure tested?**
Ambulatory surgery center; Ambulatory/office-based care; Dialysis facility; Hospital inpatient acute care facility; Nursing home

**What one healthcare domain applies to this measure?**
Safety

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

**CMIT ID**
0854

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Endorsed

**NQF ID Number**
NQF #0431

**If endorsed: Is the measure being submitted exactly as endorsed by NQF?**
Yes

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

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

**If endorsed: Year of most recent CDP endorsement**
2017

**Year of next anticipated NQF Consensus Development Process (CDP) endorsement review**
2022

**Submitter Comments**
Regarding burden, 60 minutes per facility is the estimated time to abstract data at the facility level.

*Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**

N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**

N/A

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

N/A

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

N/A

*Measure Use in CMS Programs*

**Was this measure proposed on a previous year's Measures Under Consideration list?**

No

**Previous Measure Information**

N/A

**What is the history or background for including this measure on the new measures under consideration list?**

Measure currently used in a CMS program being submitted as-is for a new or different program

**Range of years this measure has been used by CMS Programs**

- Hospital Inpatient Quality Reporting Program (2013-ongoing)
- Hospital Outpatient Quality Reporting Program (2014-2018)
- End-Stage Renal Disease Quality Incentive Program (2105-2018)
- Long-Term Care Hospital Quality Reporting Program (2014-ongoing)
- Inpatient Rehabilitation Facility Quality Reporting Program (2014-ongoing)
- Ambulatory Surgical Center Quality Reporting Program (2014-2018)
- Inpatient Psychiatric Facility Quality Reporting Program (2015-2018)
- Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program (2016-ongoing)

**What other federal programs are currently using this measure?**

Hospital Inpatient Quality Reporting Program ;Inpatient Rehabilitation Facility Quality Reporting Program;Long-Term Care (LTC) Hospital Quality Reporting Program;Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program ;Medicare Beneficiary Quality Improvement Project is using this measure for critical access hospitals

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

No

**Which measure(s) already in a program is your measure similar to and/or competing with?**

N/A

**How will this measure be distinguished from other similar and/or competing measures?**

N/A

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

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

## *Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**
From 1976-2007, influenza virus infections caused an average of 23,607 influenza-related deaths with a wide yearly range of 3,349 to 48,614 deaths over 31 influenza seasons; approximately 90% of these deaths occurred among persons aged 65 and older.(1) Healthcare personnel (HCP) can serve as vectors for influenza transmission because they are at risk for both acquiring influenza from patients and transmitting it to patients and HCP often come to work when ill.(2) One early report of HCP influenza infections during the 2009 H1N1 influenza pandemic estimated 50% of infected HCP had contracted the influenza virus from patients or coworkers in the healthcare setting.(3) Influenza virus infection is common among HCP: one study suggested that nearly one-quarter of HCP were infected during influenza season, but few of these recalled having influenza.(4) Therefore, all HCP are recommended to receive the seasonal influenza vaccine annually to protect themselves and their patients.(5)

Nosocomial influenza outbreaks in healthcare facilities result in longer stays and greater mortality for patients (6-9) and missed work for HCP.(2,9) Higher influenza vaccination coverage among HCP is associated with reductions in nosocomial influenza among hospitalized patients (8,10) and nursing home residents.(11-13) Influenza vaccination of HCP is also associated with decreased all-cause mortality among nursing home residents.(11-14)

Citations:

1. Thompson MG, Shay DK, Zhou H, et al. Estimates of deaths associated with seasonal influenza – United States, 1976-2007. MMWR Morb Mortal Wkly Rep. 2010; 59(33):1057-1062.

2. Wilde JA, McMillan JA, Serwint J, et al. Effectiveness of influenza vaccine in healthcare professionals: a randomized trial. JAMA 1999; 281: 908–913.

3. Harriman K, Rosenberg J, Robinson S, et al. Novel influenza A (H1N1) virus infections among health-care personnel – United States, April-May 2009. MMWR Morb Mortal Wkly Rep. 2009; 58(23): 641-645.

4. Elder AG, O´Donnell B, McCruden EA, et al. Incidence and recall of influenza in a cohort of Glasgow health-care workers during the 1993-4 epidemic: results of serum testing and questionnaire. BMJ. 1996; 313:1241-1242.

5. Fiore AE, Uyeki TM, Broder K, et al. Prevention and control of influenza with vaccines: Recommendations of the Advisory Committee on Immunization Practices (ACIP), 2010. MMWR Recomm Rep. 2010; 59(08): 1-62.

6. Cunney RJ, Bialachowski A, Thornley D, Smaill FM, Pennie RA. An outbreak of influenza A in a neonatal intensive care unit. Infect Control Hosp Epidemiol. 2000; 21:449-454.

7. Bridges CB, Kuehnert MJ, Hall CB. Transmission of influenza: implications for control in health care settings. Clin Infect Dis 2003; 37: 1094–1101.

8. Weinstock DM, Eagan J, Malak SA, et al. Control of influenza A on a bone marrow transplant unit. Infect Control Hosp Epidemiol. 2000; 21:730-732.

9. Sartor C, Zandotti C, Romain F, et al. Disruption of services in an internal medicine unit due to a nosocomial influenza outbreak. Infect Control Hosp Epidemiol 2002; 23:615–619.

10. Salgado CD, Giannetta ET, Hayden FG, Farr BM. Preventing nosocomial influenza by improving the vaccine acceptance rate of clinicians. Infect Control Hosp Epidemiol 2004; 25:923–928.

11. Hayward AC, Harling R, Wetten S, et al. Effectiveness of an influenza vaccine programme for care home staff to prevent death, morbidity, and health service use among residents: cluster randomised controlled trial. BMJ 2006; 333: 1241-1246.

12. Potter J, Stott DJ, Roberts MA, et al. Influenza vaccination of healthcare workers in long-term-care hospitals reduces the mortality of elderly patients. J Infect Dis. 1997; 175:1-6.

13. Lemaitre M, Meret T, Rothan-Tondeur M, et al. Effect of influenza vaccination of nursing home staff on mortality of residents: a cluster-randomized trial. J Am Geriatr Soc. 2009; 57:1580-1586.

14. Carman WF, Elder AG, Wallace LA, et al. Effects of influenza vaccination of health-care workers on mortality of elderly people in long-term care: a randomised controlled trial. Lancet 2000; 355:93–97.

### Evidence that the measure can be operationalized

There is a proven track record for CMS to obtain this data from NHSN which currently shares facility-level HCP vaccination coverage with the following CMS programs:

- Hospital Inpatient Quality Reporting Program
- Long-Term Care Hospital Quality Reporting Program
- Inpatient Rehabilitation Facility Quality Reporting Program
- Prospective Payment System-Exempt Cancer Hospital Quality Reporting Program

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

Web interface

### Feasibility of Data Elements

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home minimum data set, or MDS, home health Outcome and Assessment Information Set, or OASIS);Some data elements are in defined fields in electronic sources;No data elements are in defined fields in electronic sources

### Evidence of Performance Gap

Results of the Influenza Vaccination Coverage Among Health Care Personnel — United States, 2019–20 Influenza Season study indicate that HCP working in settings where vaccination was required reported higher vaccination coverage (94.4%) compared with settings where vaccination was not required, promoted, or offered on-site (52.3%). Among work-related characteristics, overall vaccination coverage was highest in hospital settings (93.2%) and lowest in long-term care settings (69.3%). Within work setting, vaccination coverage was highest among HCP in ambulatory care and hospital settings with

vaccination requirements (96.1% and 95.7%, respectively), and lowest in ambulatory and long-term care settings without vaccination requirements, promotion, or on-site offer (47.7% and 49.9%, respectively). Employer vaccination requirements, onsite vaccination availability and other vaccination promotions resulted in higher vaccination coverage regardless of work setting, presence of any high-risk condition, and occupation type. Findings from this survey indicate that many HCP, such as assistants/aides, other clinical personnel and non-clinical personnel, are unvaccinated, highlighting the need for more intensive interventions to improve annual influenza vaccination among different racial groups, in work settings, and in settings without employer vaccination requirements.

Link to study: https://www.cdc.gov/flu/fluvaxview/hcp-coverage_1920estimates.htm

The NHSN data reported in the "measure performance" section of this submission also provides evidence of the performance gap.

**Unintended Consequences**

The measure has been implemented; no unintended consequences have been identified.

**Outline the clinical guidelines supporting this measure**

Routine annual influenza vaccination for all persons aged =6 months who do not have contraindications has been recommended by CDC and CDC's Advisory Committee on Immunization Practices (ACIP) since 2010. Most persons who become ill with influenza virus infection recover without serious complications or sequelae. However, influenza can be associated with serious illnesses, hospitalizations, and deaths, particularly among older adults, very young children, pregnant women, and persons of all ages with certain chronic medical conditions. Influenza also is an important cause of missed work and school. Prevention of and reduction in the severity of influenza illness and reduction of outpatient illnesses, hospitalizations, and intensive care unit admissions through influenza vaccination also could alleviate stress on the U.S. health care system.

When vaccine supply is limited, vaccination efforts should focus on delivering vaccination to persons at higher risk for influenza-related complications as well as persons who live with or care for such persons, including the following:

*Health care personnel, including all paid and unpaid persons working in health-care settings who have the potential for exposure to patients or to infectious materials. These personnel might include (but are not limited to) physicians, nurses, nursing assistants, nurse practitioners, physician assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual staff, and other persons not directly involved in patient care but who can potentially be exposed to infectious agents (e.g., clerical, dietary, housekeeping, laundry, security, maintenance, administrative, and billing staff and volunteers).*

This guidance is evidence-based. The measure enhances compliance with the clinical guidelines by providing a standardized approach for healthcare providers to implement these recommendations and report coverage for vaccination among HCP, a higher risk group.

Citation: Grohskopf LA, Alyanak E, Broder KR, et al. Prevention and Control of Seasonal Influenza with Vaccines: Recommendations of the Advisory Committee on Immunization Practices — United States, 2020–21 Influenza Season. MMWR Recomm Rep 2020;69(No. RR-8):1–24. DOI: http://dx.doi.org/10.15585/mmwr.rr6908a1

**Were the guidelines graded?**
No

**If yes, who graded the guidelines?**
N/A

**If yes, what was the grade?**
N/A

**Estimated Impact of the Measure: Estimate of Annual Denominator Size**
Actual annual denominator size for facilities that submitted NHSN data in 2020.

Acute care hospitals:

All HCP, n= 4,461 facilities

Employees, n=4,461 facilities

Inpatient rehabilitation facilities:

All HCP, n=1,053 facilities

Employees, n=1,053 facilities

Long-term acute care hospitals:

All HCP, n= 379 facilities

Employees, n= 379 facilities

**Estimate of Annual Improvement in Measure Score**
Actual percentage change calculated using data submitted to NHSN. Year=2020 (10/1/2020-3/31/2021) VS 2019 (10/1/2019-3/31/2020).

Acute care hospitals:

All HCP, -4.8%

Employees, -4.6%

Inpatient rehabilitation facilities:

All HCP, -3.9%

Employees, -4.5%

Long-term acute care hospitals:

All HCP, -5.8%

Employees, -6.0%

**Type of Evidence to Support the Measure**
Clinical Guidelines; Empirical data

**Is the measure risk adjusted, stratified, or both?**
None

**Are social determinants of health built into the risk adjustment model?**
Not Applicable

**Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event**
Unable to determine

**Cost Avoided Annually by Medicare/Provider**
Unable to determine

**Source of Estimate**
Not applicable

**Year of Cost Literature Cited**
Not applicable

*Patient and Provider Perspective*

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

**If yes, choose all methods of obtaining patient/caregiver information**
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

**How many times and at what phase(s) of measure development was the patient/caregiver engaged?**
Once during conceptualization

**Total Number of Patients and/or Caregivers Consulted**
9

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

**Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions**
9

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

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

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

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

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

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

**Total Number of Clinicians/Providers Consulted**
318

**Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care**
298

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

**If yes, how many sites were evaluated in the provider workflow analysis?**
318

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

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

**Does the measure require manual abstraction?**
Yes

**If yes, what is the estimated time per record to abstract data?**
0

**How many data elements will be collected for the measure?**
15

*Measure Testing Details*

**Reliability Testing Interpretation of Results**
Results demonstrate high reliability and validity for numerator data reported for employees vaccinated at the facility and elsewhere. Adhering to true medical contraindications and tracking declinations should improve reliability.

**Type of Reliability Testing**
Data Element Reliability

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

**Reliability Testing Sample Size**
96 facilities

**Reliability Testing Statistical Result**

Overall adjusted agreement between facility staff and project staff was 91% for numerator data and 96% for denominator data. Raters agreed on the numerator status for 99% of the records selected for HCP vaccinated at the facility, 95% of HCP vaccinated elsewhere, 64% of HCP with medical contraindications, and 64% of HCP who declined vaccination.

| | Numerator | Denominator |
|---|---|---|
| | Adjusted % agreement, Adjusted kappa* (95% CI) | Adjusted % agreement, Adjusted kappa* (95% CI) |
| Acute care hospitals | | |
| | 99 0.96 (0.94–0.98) | 95 0.93 (0.91–0.95) |
| Long-term care facilities | | |
| | 96 0.93 (0.90–0.96) | 99 0.96 (0.94–0.98) |
| Ambulatory surgery centers | | |
| | 87 0.72 (0.65–0.79) | 79 0.51 (0.42–0.61) |
| Physician practices | | |
| | 84 0.63 (0.58–0.69) | 95 0.44 (0.27–0.67) |
| Dialysis centers | | |
| | 77 0.55 (0.50–0.60) | 99 0.96 (0.92–1.00) |

*kappa values and percent agreement have been adjusted by assigning a weight of 0 to records classified by the institution as missing or uncertain.

**Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?**

Yes

**If yes, specify the number of cases and the percentage of providers**

60

**Type of Validity Testing**

Data Element Validity

**Validity Testing: Type of Validity Testing Analysis**

Face Validity

**Validity Testing Sample Size**

Facilities, n=23; Experts, n=9

**Validity Testing Statistical Result**

Face validity: Panel of 9 experts

The degree of consensus was based on likert scale results. The modified Delphi panel of 9 experts reached consensus on the validity of the following numerator definitions: influenza vaccination received

at the facility, documented receipt of influenza vaccination outside the facility, documented receipt of a medical contraindication to vaccination, and documented declination of vaccine for nonmedical reasons, including religious exemptions.

Experts reached the strongest consensus on the validity of the following denominator definitions: credentialed nonemployees defined as nonemployee physicians, advanced practice nurses, and physician assistants working at the facility for 30 or more days between October 1 and March 31 of the following year; other nonemployees defined as students and volunteers working at the facility for 30 or more days between October 1 and March 31 of the following year; and other nonemployees defined as all nonemployees who are required by the facility to undergo a periodic skin test for tuberculosis

Validity was lowest for credentialed and other nonemployees.

**Validity Testing Interpretation of Results**

The standardized measure of HCP influenza vaccination yields reproducible results for employees vaccinated at the facility and elsewhere. Results demonstrate high validity for numerator data reported for employees vaccinated at the facility and elsewhere. Difficulties in establishing denominators and determining vaccination status for credentialed and other nonemployees challenged the measure's validity and prompted revision to include a more limited group of nonemployees.

**Measure performance – Type of Score**

Proportion

**Measure Performance Score Interpretation**

Higher score is better

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

Current data reported to NHSN web-based surveillance system for the period covering October 1, 2020-March 31, 2021. Notes: AS, GU, PR and VI removed from analysis; denominator = 0 removed from analysis.

Acute care hospitals:

All HCP (n=4,461) Mean-84.4%, SD-15.2%, Min-1.8%, Max-100%, IQR-18.7%, Q1-77.4%, Q3, 96.1%
[Note: excluded 5 org IDs with denominator =0]

Employees: (n=4,461) Mean-86.5%, SD-14.1%, Min-0.0%, Max-100%, IQR-17.0%, Q1-80.1%, Q3, 97.1%
[Note: excluded 5 org IDs with denominator =0]

Inpatient rehabilitation facilities:

All HCP (n=1,055) Mean-85.4%, SD-16.1%, Min-1.8%, Max-100%, IQR-18.2%, Q1-78.9%, Q3, 97.1%
[Note: excluded 11 org IDs with denominator =0]

Employees: (n=1,053) Mean-85.9%, SD-15.8%, Min-1.9%, Max-100%, IQR-16.8%, Q1-80.3%, Q3, 97.1%
[Note: excluded 13 org IDs with denominator =0]

Long-term acute care hospitals

All HCP (n=379) Mean-77.5%, SD-19.2%, Min-0.0%, Max-100%, IQR-25.4%, Q1-67.8%, Q3, 93.2%

Employees: (n=379) Mean-80.0%, SD-18.6%, Min-0.0%, Max-100%, IQR-23.9%, Q1-67.8%, Q3, 94.9%

**Benchmark, if applicable**
Not applicable

## *Measure Contact Information*

**Measure Steward**
Centers for Disease Control and Prevention;Centers for Disease Control and Prevention

**Measure Steward Contact Information**
Megan Lindley

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**Long-Term Measure Steward**
N/A

**Long-Term Measure Steward Contact Information**
N/A

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## Section 2: Preliminary Analysis – MUC2021-123 Influenza Vaccination Coverage among Healthcare Personnel

**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 measures addressing influenza vaccine coverage currently in the Skilled Nursing Facility Quality Reporting Program (SNF QRP) set. This is a NQF endorsed measure utilized in two other PAC/LTC programs, Long-Term Care Hospital Quality Reporting Program (LTCH QRP) and Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP). Vaccine coverage among healthcare personnel within Skilled Nursing Facilities (SNFs) is of importance as seen by the recently adopted COVID-19 Healthcare Personnel (HCP) Vaccine measure.

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

**Yes/No:** Yes

**Justification and Notes:** Estimates of recent years indicate 70 to 85 percent of seasonal flu-related death were those 65 years and older, and 50 to 70 percent of seasonal flu-related hospitalization were among the same age group (Centers for Disease Control and Prevention, 2021). The developer cites numerous evidence indicating increased influenza vaccine rates among HCP contribute to decreased morbidity and mortality among patients. Specifically, the developer cites evidence demonstrating influenza vaccination of HCP is associated with reductions in nosocomial influenza among nursing home residents and decreased all-cause mortality among nursing home residents.

**Does the measure address a quality challenge?**

**Yes/No:** Yes

**Justification and Notes:** Influenza affects older adults disproportionately and healthcare personnel can aid in this transmission. The Advisory Committee on Immunization Practices (ACIP) recommends vaccination for healthcare personnel and indicates reduction of influenza illness could alleviate stress on the U.S. healthcare system caused by the SARS-CoV-2 Public Health Emergency (PHE) (Centers for Disease Control and Prevention, 2021). The developer notes influenza vaccination coverage is lowest, 49.9 percent, in long-term care settings without vaccine requirements, promotion, or on-site offering. The developer indicates recent data 10/1/2020 to 3/1/2021 from the National Healthcare Safety Network (NHSN). This data reports influenza vaccination of HCP in long-term acute care hospitals with a mean of 77.5 percent, an interquartile range (IQR) of 25.4 percent, and an actual percentage change of 5.8 percent.

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

**Yes/No:** Yes

**Justification and Notes:** There are no other measures addressing influenza vaccine coverage in the SNF QRP set. The measure is currently utilized in the LTCH QRP and IRF QRP. These two program sets, along with the recently adopted COVID-19 HCP Vaccine measure within the SNF QRP, align the PAC/LTC programs with the importance of healthcare personnel vaccine coverage.

### Can the measure be feasibly reported?

**Yes/No:** Yes

**Justification and Notes:** The developer indicates all data elements are in defined fields in electronic data sources. CMS utilizes the NHSN for Healthcare Personnel (HCP) vaccine data collection in other PAC/LTC programs. Skilled Nursing Facilities (SNFs) will utilize NHSN for the recently adopted COVID-19 HCP Vaccine 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:** This NQF-endorsed measure is specified and originally tested at the facility-level of analysis with skilled nursing facilities as the care setting. The target population is healthcare personnel. The most recent performance at the facility-level of analysis was with acute care hospitals, inpatient rehabilitation facilities, and long-term acute care hospitals as the care settings. Utilizing NHSN data, influenza vaccine coverage was lowest, 77.5 percent, within the long-term acute care 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:** This measure is in current use within the LTCH QRP and IRF QRP. No unintended consequences have been identified. The most recent NQF endorsement publication, Health and Well-Being 2015-2017, indicated public comments of recommendation for continued endorsement. The original MAP Report, MAP Pre-Rulemaking Report: 2013 Recommendations on Measures Under Consideration by HHS, indicated support for the measure in the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and additional findings for application across all PAC/LTC programs.

### PAC/LTC Core Concept?

**Yes/No:** No

**Justification:** This measure does not meet one of the 13 PAC/LTC core concepts. Per the final report, vaccination measures were not mapped to a core set concept (National Quality Forum, 2012).

### Impact Act Domain

**Yes/No:** No

**Justification:** This measure does not meet one of the 8 Impact Act domains. Vaccination and safety are not one of the addressed domains (Centers for Medicare & Medicaid Services, 2014).

### Hospice High Priority Areas

**Yes/No:** N/A

**Justification:** N/A

### MAP Rural Health Advisory Group Input:

**Relative priority/utility:**

- It is rural relevant and it is an important topic for rural providers and healthcare personnel
- The Advisory Group generally agreed with the importance of this measure and relevance to rural providers and care settings

**Data collection issues:**

- None

**Calculation issues:**

- None

**Unintended consequences:**

- An Advisory Group member noted there may be concerns around vaccinations measures in general. Given the challenges with the COVID vaccination in health care facilities, this measure might also be challenging to implement for the rural setting in particular
- An Advisory Group member also noted the challenges with workforce and staffing in rural care settings, and encouraged CMS to monitor for unintended negative consequences to rural providers

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 4.5
1 – 0 votes
2 – 0 votes
3 – 0 votes
4 – 7 votes
5 – 8 votes

### MAP Health Equity Advisory Group Input:

**Relative priority/utility:**

- Important public health priority, not sure if there are any equity concerns

**Data collection issues:**

- Discussion on what is available for the public and what is reported to CMS. The measure steward clarified that what is sent CMS and what is publicly reported is overall compliance

**Calculation issues:**

- None

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 3.8
1 – 0 votes
2 – 0 votes
3 – 7 votes
4 – 15 votes
5 – 2 votes

*Recommendation*

**Preliminary Analysis Recommendation:**

Support for Rulemaking

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

This measure adds value to the SNF QRP set by adding a measure not currently addressed within the program, and this measure aligns with other PAC/LTC programs utilizing the same measure. Vaccination coverage among HCP within SNFs is of importance as seen by the recently adopted COVID-19 Healthcare Personnel Vaccine measure. Vaccination coverage among HCP within these facilities can decrease its viral transmission, along with a decrease in morbidity and mortality among patients. There is variation in the performance of this measure within SNFs and these facilities will have the ability to implement interventions to improve performance.

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

Influenza affects older adults disproportionately and healthcare personnel can aid in this transmission. Estimates of recent years indicate 70 to 85 percent of seasonal flu-related death were those 65 years and older, and 50 to 70 percent of seasonal flu-related hospitalization were among the same age group (Centers for Disease Control and Prevention, 2021). Recent data from the NHSN reports influenza vaccination of HCP in long-term acute care hospitals a mean of 77.5 percent and a year-over-year actual percentage change of 5.8 percent. Besides increased patient morbidity and mortality, healthcare facility influenza outbreaks lead to longer patient stays. Increased influenza vaccine rates among healthcare personnel can help to improve care for patients.

## Section 3: Public Comments

**American Health Care Association**

This measure should seek NQF endorsement for use in the QRP program. The measure is part of the suite of measures as part of the IMPACT act, which is to have standard measures across the four post acute care settings. Currently, IRF and LTCH have a measure but SNFs and Home health do not. It's an important measure and should be added to the QRP program since it already is in use in two other PAC providers. Home Health should also have this measure added.

**LeadingAge**

LeadingAge agrees that it is important for healthcare personnel to obtain their vaccines to prevent the spread of viruses within nursing homes. However, we don't believe the administrative burden to report into NHSN outweighs the benefits at this time. Reporting through NHSN is highly burdensome and would require additional staffing to track this information at a time when we are already struggling to hire and retain staff during a pandemic. Again, if CMS would like providers to report into NHSN on a variety of measures in the future, we would ask that they first spend time to streamline this reporting with other state and/or county-level reporting where nursing homes are often reporting the same information. These duplicative reporting processes require additional staff time to be dedicated to these tasks.

**Johnson & Johnson**

Johnson & Johnson supports the MAP's recommendation to move forward with rulemaking for this

measure. Johnson & Johnson supports measures that incentivize guideline concordant vaccination among healthcare personnel and increase facility vaccination rates. As the COVID-19 pandemic has made clear, it is more important than ever to focus on vaccinating health care personnel, particularly against highly transmissible respiratory conditions. Further, as we have also witnessed during the pandemic, workforce shortages resulting from infected personal stress the system and put patient care in jeopardy. This measure will help encourage vaccination rates and will help to stop the spread of disease within the workforce, and between the workforce and patients. Johnson & Johnson further encourages NQF and CMS to consider developing similar measures as new vaccines become available to treat other highly transmissible viruses.

### American Hospital Association

The AHA agrees with the MAP's recommendation of Support for this measure. The measure is endorsed by the NQF and has been used in CMS quality reporting programs in the past, demonstrating its feasibility. Vaccination among health care personnel serving SNF residents is of extreme importance considering the vulnerable state of SNF residents as well as the high rate of viral transmission in residential facilities. The topic is valuable to patients and the community and the measure steward has demonstrated variation in performance on this measure across the country, so use of this measure is likely to result in improved rates of vaccination.

MUC2021-098 National Healthcare Safety Network (NHSN) Healthcare-associated Clostridioides difficile Infection Outcome Measure

## Section 1: Measure Information

### *Measure Specifications and Endorsement Status*

**Program**

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

**Workgroup**

PAC/LTC

**Measure Description**

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

**Numerator**

Healthcare-Associated Clostridioides difficile Infection (HA-CDI):

Total observed number of observed Clostridioides difficile infections among all inpatients in the facility, as defined as either of the below definitions.

HA-CDI 1: must meet BOTH A & B.

A) Any C. difficile (CD) positive laboratory assay from a stool specimen, including initial and final tests in a testing algorithm.

B) Administration of oral or rectal vancomycin or fidaxomicin within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

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

A) Final positive test from a C. difficile (CD) laboratory assay from a stool specimen in a testing algorithm.

B) Administration of oral or intravenous metronidazole within the window period extending 2 calendar days before and 2 calendar days after the date of stool specimen collection in part A.

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

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

**Denominator Exclusions**
Data from patients who are not assigned to an inpatient bed in an applicable location are excluded from the denominator counts, including outpatient clinic and emergency department visits. Additionally, data from well-baby nurseries and NICUs are excluded from the denominator count.

Denominator counts exclude data from inpatient rehabilitation units and inpatient psychiatric units with unique CMS Certification Numbers (CCN) than the acute care facility.

**Denominator Exceptions**
Under investigation, subject to change.

**State of development**
Specification

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

**What is the target population of the measure?**
All Payer

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

**Measure Type**
Outcome

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

**If Other, Please Specify**
N/A

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

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

**If EHR or Chart-Abstracted data, description of parts related to these sources**
1) Microbiology records of stool tests for C. difficile, typically from an EHR laboratory information system.

2) Medication administration records (eg. antimicrobial administration), from EHR.

3) Administration records, non-claims (eg. date of admission, discharge, patient location).

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

**At what level of analysis was the measure tested?**
Facility

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

**What one healthcare domain applies to this measure?**
Safety

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

**CMIT ID**
N/A

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Never Submitted

**NQF ID Number**
N/A

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

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

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

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

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

**Submitter Comments**
N/A

*Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

*Measure Use in CMS Programs*

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

**Previous Measure Information**
N/A

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

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

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

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

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

**How will this measure be distinguished from other similar and/or competing measures?**
The current NHSN measure is based on laboratory results, and C. difficile is typically diagnosed using non-culture based diagnostic tests which have wide variation in sensitivity and in rates of false positives.

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

**How will this measure add value to the CMS program?**

This new measure increases the clinical validity of original measure, and therefore more accurately reflect the presence of clinical infection and quality measurement.

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

N/A

## *Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**

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

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

References

(1) Centers for Disease Control and Prevention. CDC Antibiotic Resistance & Patient Safety Portal, accessed May 2, 2021, available at https://arpsp.cdc.gov/profile/infections/CDI

(2) Rock C, Pana Z et al. National Healthcare Safety Network laboratory-identified Clostridium difficile event reporting: A need for diagnostic stewardship. American Journal of Infection Control, 2018. ISSN: 0196-6553, Vol: 46, Issue: 4, Page: 456-458

(3) Centers for Disease Control and Prevention. Short Summary: Testing for C. difficile and Standardized Infection Ratios, National Healthcare Safety Network, 2019. Published November 2019, available at https://www.cdc.gov/nhsn/pdfs/ps-analysis-resources/Cdiff-testing-sir-508.pdf

(4) Thure K, Fell A. Improving HAI surveillance: lessons learned from NHSN Data Validation. Presented at Association for Professionals in Infection Control and Epidemiology Annual Conference; June 2018; Minneapolis, MN

(5) McDonald LC, Gerdling DN et al. Clinical Practice Guidelines for Clostridium difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA) Clinical Infectious Diseases. Volume 66, Issue 7, 1 April 2018, Pages e1–e48

**Evidence that the measure can be operationalized**

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

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

Other: CDC NHSN submission to CMS

**Feasibility of Data Elements**

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

**Evidence of Performance Gap**

Analysis forthcoming.

**Unintended Consequences**

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

**Outline the clinical guidelines supporting this measure**

N/A

**Were the guidelines graded?**

N/A

**If yes, who graded the guidelines?**

N/A

**If yes, what was the grade?**

N/A

**Estimated Impact of the Measure: Estimate of Annual Denominator Size**

Approximately 38 million admissions currently subject to CDC NHSN surveillance (2019 data).

**Estimate of Annual Improvement in Measure Score**

To be determined.

**Type of Evidence to Support the Measure**
Empirical data

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

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

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

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

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

**Year of Cost Literature Cited**
October 2015 through June 2019.

*Patient and Provider Perspective*

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

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

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

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

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

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

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

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

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

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

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

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

**Total Number of Clinicians/Providers Consulted**
N/A

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

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

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

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

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

**Does the measure require manual abstraction?**
No

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

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

*Measure Testing Details*

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

**Type of Reliability Testing**
Measure Score Reliability

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

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

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

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

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

**Type of Validity Testing**
N/A

**Measure Score Validity**
N/A

**Validity Testing: Type of Validity Testing Analysis**
Construct Validity

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

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

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

**Measure performance – Type of Score**
Ratio

**Measure Performance Score Interpretation**
Lower score is better

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

Standardized Infection Ratios (SIR) for annual and quarterly data aggregation and analysis of HA-CDI events will be calculated for each healthcare facility for a specified time period. The SIR is an indirect

standardization method for summarizing healthcare associated infection (HAI) experience, in a single group of data or across any number of stratified groups of data. To produce an SIR we will:

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

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

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

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

**Benchmark, if applicable**
See methods above for calculation of SIR and ARM.

## *Measure Contact Information*

**Measure Steward**
Centers for Disease Control and Prevention

**Measure Steward Contact Information**
Raymund Dantes

1600 Clifton Rd

Atlanta, GA 30333

vic5@cdc.gov

800-232-4636

**Long-Term Measure Steward**
Centers for Disease Control and Prevention

**Long-Term Measure Steward Contact Information**
Andrea Benin

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Atlanta, GA 30333

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800-232-4636

**Primary Submitter Contact Information**
N/A

**Secondary Submitter Contact Information**
N/A

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

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

**Justification and Notes:** There are no measures that address Healthcare-Associated Clostridioides difficile Infections (HA-CDIs) within the Skilled-Nursing Facility Quality Reporting Program (SNF QRP). The recently adopted Skilled-Nursing Facility Healthcare-Associated Infections Requiring Hospitalization measure will begin with FY 2023. The recently adopted measure is not infection specific and includes those incidences requiring hospitalization. The MUC calculates the observed number of HA-CDIs at the skilled-nursing facility, divided by the number of infections expected based on facility characteristics. Measuring healthcare-associated infections remains a high priority for the Skilled-Nursing Facility Quality Reporting Program (SNF QRP) and safety is a CMS Meaningful Measures 2.0 focus.

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

**Justification and Notes:** After several years of implementation of HA-CDI quality measures, a 60 percent decrease in reported HA-CDIs within Long-Term Care Acute Hospitals (LTCAHs) was observed from 2015-2020 (Centers for Disease Control and Prevention, 2021). This indicates LTCAHs have successfully implemented initiatives, such as CDC's guidelines for hand hygiene, that are reducing infection rates (2002). This measure is intended to capture HA-CDIs specifically, instead of the recently adopted non-specific infection measure.

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

**Justification and Notes:** HA-CDIs are serious adverse events for patients, and can result in death. In 2020, nearly 114,000 HA-CDIs were reported to the CDC (2021). CDC guidelines assign the high grade, 1A, to recommendations to monitor the incidence of HAIs such as CDI, and to leverage that information to guide infection control procedures (2019). According to National and State Healthcare-Associated Infections reports, in 2020 the 20$^{th}$ percentile of performance for long-term care hospitals was .094 infections observed/expected, compared to an 80$^{th}$ percentile performance of .687 infections observed/expected, indicating a substantial range in performance (CDC, 2021).

**Does the measure contribute to efficient use of measurement resources and/or support alignment of measurement across programs?**
**Yes/No:** Yes

**Justification and Notes:** There are no other measures addressing HA-CDIs at the SNF level in the SNF QRP set. Versions of the same HA-CDI monitoring measure are also currently in use for quality reporting programs for acute care hospitals and inpatient rehabilitation facilities.

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

**Justification and Notes:** All data elements required to calculate the measure are available in defined fields in electronic data. Another HA-CDI measure currently implemented in the Long-Term Care Hospital Quality Reporting Program (LTCH QRP) has been successfully submitted by hundreds of long-term care hospitals for several years.

**Is the measure applicable to and appropriately specified for the program's intended care setting(s), level(s) of analysis, and population(s)?**
**Yes/No:** No

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

**If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?**
**Yes/No:** N/A

**Justification and Notes:** The measure is not currently in use. This MUC is similar to a prior measure submitted for CDP endorsement (NQF #3556), but did not pass the Spring 2020 Scientific Methods Panel on both reliability and validity. The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test for CDI AND a treatment administered. This update is intended to mitigate instances where a facility or provider might be incentivized not to test for a suspected HA-CDI.

### PAC/LTC Core Concept?

**Yes/No:** Yes

**Justification:** This measure meets one of the 13 core concepts, infection rates, which specifically indicates HAIs on the core concept list.

### Impact Act Domain

**Yes/No:** No

**Justification:** This measure does not meet one of the 8 Impact Act domains.

### Hospice High Priority Areas

**Yes/No:** N/A

**Justification:** N/A

### MAP Rural Health Advisory Group Input:

**Relative priority/utility:**

- HAIs are extremely important to monitor

**Data collection issues:**

- None

**Calculation issues:**

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

**Unintended consequences:**

- None

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

Average: 4.0
1 – 0 votes
2 – 0 votes
3 – 1 votes
4 – 9 votes
5 – 1 votes

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

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 3.5
1 - 0 votes
2 - 2 votes
3 - 5 votes
4 - 9 votes
5 - 1 vote

## *Recommendation*

**Preliminary Analysis Recommendation:**

Conditional Support for Rulemaking, pending NQF endorsement and successful testing of reliability and validity.

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

This measure adds value to the SNF QRP set by adding a measure not currently addressed within the program, and this measure aligns with other PAC/LTC programs utilizing a similar measure. The updated specifications of this HA-CDI measure are intended to mitigate unintended consequences by only counting those cases where there is evidence of both a positive test for CDI AND a treatment administered, which may have led to a historical under-counting of observed HA-CDI. Healthcare-associated infections are of importance to SNFs as seen by the recently adopted SNF HAIs Requiring Hospitalizations measure. Measuring healthcare-associated infections remains a high priority for the SNF QRP and safety is a CMS Meaningful Measures 2.0 focus.

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

A HA-CDI has serious potential consequences for patients, including death. Nearly 114,000 HA-CDIs were reported to the CDC in 2020. The performance of long-term care hospitals on the existing HA-CDI measure shows considerable variation in performance: the 20th percentile of performance for long-term care hospitals was .094 infections observed/expected, compared to an 80th percentile performance of .687 infections observed/expected. Nevertheless, this performance has improved by 60 percent over the prior five years, as the quality measure has incentivized the implementation of hand hygiene, isolation, and other protocols recommended by CDC guidelines.

The conditions for Support for Rulemaking are for the measure to be submitted to NQF for endorsement, as well as for reliability and validity testing to be successfully completed.

## Section 3: Public Comments

### American Health Care Association

We do not support this measure principally for four reasons: (1) This measure failed reliability and validity review by NQF in April 2020 under measure #3556. However the documents state this measure has not undergone NQF endorsement review. (2) this measure justifications, specifications, descriptions all related to the hospital or LTCH setting and none to the SNF setting. For example the exclusions are for neonatal admissions. (3) This measure does not appear to exclude or take into consideration C dff cases that were acquired in the hospital prior to discharge to the SNF. (4) the risk adjustment for this measure is not specified and earlier versions of this measure only risk adjusted for facility characteristics not patient characteristics; and (5) this measure also requires level III SAM certification to submit data to CDC NHSN. it currently takes a minimum of 6 weeks to receive certification which is assigned to an individual not a facility. Thus, if the person leaves the facility can't submit data for at least 6 weeks. With high turnover in SNFs, this is a frequent occurrence. CMS recently delayed requirement that SNFs have staff receive level III SAM clearance. Failure to submit data under QRP results in a 2% cut to Medicare payments

### LeadingAge

LeadingAge would support this measure for inclusion in the SNF QRP, given the prevalence of the condition is significantly higher in hospitals and nursing homes versus the community, the fact that the outcomes can be impacted through infection prevention measures and appropriate antibiotic use; and that there is variation in the results of this measure among nursing homes. However, even though we understand the clinical importance of this measure, we believe the burden of reporting into NHSN does not warrant implementing at this time. We would like to see CMS and NHSN first work with the states and counties to encourage their use of the NHSN reporting modules instead of requiring separate and often duplicative reporting. At present, many providers have to report the same information to NHSN, their state and their county. Until this process is streamlined, we do not recommend adding this measure to the SNF QRP. Our preference would be if this measure is to become part of SNF QRP that this measure is captured via existing data such as MDS or claims, instead of the additional administrative burden of reporting through NHSN.

### American Health Care Association

This measure or similar version failed NQF review in April 2020 (#3556) and its unclear what changes were made with this new version. All the measure justifications are for other settings and none provided for SNFs, the risk adjustment is not specified. Its unclear if it excludes C diff present at admission.

## Skilled Nursing Facility Value-Based Purchasing Program

MUC2021-095 CoreQ: Short Stay Discharge Measure

# Section 1: Measure Information

*Measure Specifications and Endorsement Status*

**Program**
Skilled Nursing Facility Value-Based Purchasing Program

**Workgroup**
PAC/LTC

**Measure Description**
The measure calculates the percentage of individuals discharged in a six month time period from a SNF, within 100 days of admission, who are satisfied (scoring a 3 or above on the survey).

**Numerator**
The measure assesses the number of patients who are discharged from a SNF, within 100 days of admission, who are satisfied. The numerator is the sum of the individuals in the facility that have an average satisfaction score equal to or greater than 3 for the four questions on the CoreQ: Short Stay Discharge questionnaire.

**Numerator Exceptions**
Respondents with average score less than 3.0.

**Denominator**
The denominator includes all of the patients that are admitted to the SNF, regardless of payor source, for post-acute care, that are discharged within 100 days; who receive the survey (e.g. people meeting exclusions do not receive a questionnaire) and who respond to the CoreQ: Short Stay Discharge questionnaire within the time window.

**Denominator Exclusions**
Exclusions used are made at the time of sample selection and include:

(1) Patients who died during their SNF stay;
(2) Patients discharged to a hospital, another SNF, psychiatric facility, inpatient rehabilitation facility or long term care hospital;
(3) Patients with court appointed legal guardian for all decisions;
(4) Patients discharged on hospice;
(5) Patients who left the nursing facility against medical advice (AMA);
(6) Patients who have dementia impairing their ability to answer the questionnaire defined as having a BIMS score on the MDS as 7 or lower. [Note: we understand that some SNCCs may not

have information on cognitive function available to help with sample selection. In that case, we suggest administering the survey to all residents and assume that those with cognitive impairment will not complete the survey or have someone else complete on their behalf which in either case will exclude them from the analysis.]

(7) Patients who responded after the two month response period; and
(8) Patients whose responses were filled out by someone else.

**Denominator Exceptions**
N/A

**State of development**
Fully Developed

**State of Development Details**

**What is the target population of the measure?**
All short-stay (less than 100 days_ patients for short-term SNF care regardless of payer status

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

**Measure Type**
Patient Engagement/Experience

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

**If Other, Please Specify**
N/A

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

**If applicable, specify the data source**

**If EHR or Chart-Abstracted data, description of parts related to these sources**
BIMS score, admission date, discharge date and destination for sample selection

**At what level of analysis was the measure tested?**
Facility;Other: Resident

**In which setting was this measure tested?**
Nursing home;Skilled nursing facility

**What one healthcare domain applies to this measure?**
Person-Centered Care

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

**CMIT ID**
N/A

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Endorsed

**NQF ID Number**
NQF #2614

**If endorsed: Is the measure being submitted exactly as endorsed by NQF?**
Yes

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

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

**If endorsed: Year of most recent CDP endorsement**
2020

**Year of next anticipated NQF Consensus Development Process (CDP) endorsement review**
2023

**Submitter Comments**
CoreQ: Short Stay Discharge measure is one of 5 measures (CoreQ long-stay family and resident and CoreQ assisted living family and resident). All CoreQ Measures have been NQF endorsed, are being used nationally, and have been adopted in some states for VBP and AL satisfaction reporting. There are currently 38 national satisfaction vendors who have incorporated CoreQ into their satisfaction surveys.

## *Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

*Measure Use in CMS Programs*

**Was this measure proposed on a previous year's Measures Under Consideration list?**
Yes

**Previous Measure Information**
Year: 2017

Measure ID: MUC17-258

Workgroup: Post-Acute Care and Long-Term Care

Program: SNF QRP

Recommendation: Support

Not Recommended: N/A

Report Page Number: 20 of 95

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

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

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

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

**Which measure(s) already in a program is your measure similar to and/or competing with?**
N/A

**How will this measure be distinguished from other similar and/or competing measures?**
N/A

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

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

*Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**
Please see attachment: CoreQ_Short_Stay_Evidence_Final_April2020

### Evidence that the measure can be operationalized

CoreQ: Short Stay Discharge Measure is a four-question survey that can be added to an existing satisfaction survey or conducted independently. Several additional questions about the respondent completing the questionnaire should be collected as they are required in the analysis of the measure. These include questions about any help the respondent received in completing the questionnaire and who helped complete the questionnaire. If these are already included in an existing questionnaire that the CoreQ is being added to, then use those questions. The data collection instrument used for exclusions used for this measure is the Minimum Data Set 3.0 (MDS 3.0).

CoreQ is widely used across long term care (SNF, Short-Stay, and assisted living). Currently, several states utilize the CoreQ and the CoreQ team has worked with these states including New Jersey, Oregon, Washington, Massachusetts, and Rhode Island to adopt CoreQ in their state satisfaction reporting programs. New Jersey and Tennessee have implemented CoreQ for their SNF Quality Incentive Payment Program. Oregon has approved CoreQ Assisted Living Family and Resident satisfaction measures to be publicly reported. A workgroup in Washington has recommended CoreQ to be used in their publicly reported data for assisted living.

Currently, 38 Satisfaction vendors have incorporated or will incorporate CoreQ in their surveys when asked by clients. The list can be found at CoreQ.org.

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

Web interface

### Feasibility of Data Elements

ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home minimum data set, or MDS, home health Outcome and Assessment Information Set, or OASIS);Patient/family-reported information: electronic;Patient/family-reported information: paper

### Evidence of Performance Gap

The distribution of the summary score is wide with no ceiling or floor effects, indicating opportunities for improvement. Examples of data demonstrating this are from our data management system, LTC Trend Tracker.

Data covers 2016Q1-2019Q4

Number of SNFs ranges from 372-1577

Mean Satisfaction Rate ranges from 77.1-85.83% between quarters, but generally fluctuates between 77-80%

SD ranges from 14.39-18.90%

Vendor data from MA, NJ, PA, IL, NY providers (not included in above data)

Data covers 2019Q1 and 2019Q2

Number of SNFs = 831

Mean Satisfaction Rate ranges 74.15-84.98% between quarters SD ranges from 10.33-14.60%

See attachment: Appendix

**Unintended Consequences**
There were no unintended consequences – no potentially serious physical, social, legal, psychological, or other risk for the patients. In some cases, the questionnaire could highlight poor care for some dissatisfied residents which could cause further dissatisfaction.

**Outline the clinical guidelines supporting this measure**
N/A

**Were the guidelines graded?**
N/A

**If yes, who graded the guidelines?**
N/A

**If yes, what was the grade?**
N/A

**Estimated Impact of the Measure: Estimate of Annual Denominator Size**
218,503 from data provided to AHCA/NCAL

**Estimate of Annual Improvement in Measure Score**
Through the AHCA Quality Initiative, the goal was set to achieve greater than a 90% satisfaction rating or increase by 10% within the 3 year timeframe.

**Type of Evidence to Support the Measure**
Systematic Review;Empirical data

**Is the measure risk adjusted, stratified, or both?**
None

**Are social determinants of health built into the risk adjustment model?**
Not Applicable

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

**Cost Avoided Annually by Medicare/Provider**
N/A

**Source of Estimate**
N/A

**Year of Cost Literature Cited**
N/A

*Patient and Provider Perspective*

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

**If yes, choose all methods of obtaining patient/caregiver information**
Focus groups;One-on-one interviews;Surveys

**How many times and at what phase(s) of measure development was the patient/caregiver engaged?**
Patients have been engaged from the development, testing, and continuously as they are asked feedback on the survey. Meaningfulness was determined using 40 residents in five nursing facilities in the Pittsburgh area.

**Total Number of Patients and/or Caregivers Consulted**
40

**Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups**
5/1

**Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions**
40

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

**If yes, what is the estimated time to complete the survey?**
5

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

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

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

**If yes, choose all methods that obtained clinician and/or provider input**
Surveys;One-on-one interviews;Focus groups

**Total Number of Clinicians/Providers Consulted**
20

**Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care**
20

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

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

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

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

**Does the measure require manual abstraction?**
No

**If yes, what is the estimated time per record to abstract data?**

**How many data elements will be collected for the measure?**
5

*Measure Testing Details*

**Reliability Testing Interpretation of Results**
The measure displays a high degree of element-level, questionnaire-level, and measure (facility)-level reliability. First, the CoreQ: Short Stay Discharge questionnaire data elements were highly repeatable, with pilot and re-administered responses agreeing between 94% and 97% of the time, depending on the question. That is, this produced the same results a high proportion of the time when assessed in the same population in the same time period. Second, the questionnaire level scores were also highly repeatable, with pilot and re-administered responses agreeing 98% of the time. Third, a facility drawing patients from the same underlying population only varied modestly. The 10,000-repetition bootstrap results showed that the CoreQ: Short Stay Discharge measure scores from the same facility are very stable, given the minimum sample size of 20 we set for this measure; and the maximum sample size of 196.

**Type of Reliability Testing**
Measure Score Reliability; Data Element Reliability

**Reliability Testing: Type of Testing Analysis**
Test-Retest;Other: Bootstrapping - 10,000 repititions

**Reliability Testing Sample Size**
853 patients and 100 for re-survey

**Reliability Testing Statistical Result**
We measured reliability at the: (1) data element level; (2) the person/questionnaire level; and, (3) at the measure (i.e., facility) level.

**(1) DATA ELEMENT LEVEL**

The responses in the pilot survey were not statistically significant from the re-administered survey. This shows that the data elements were highly repeatable and produced the same results a high proportion of the time when assessing the same population in the same time period. The average of the percent agreement from the first survey score to the second survey score for each item in the CoreQ: Short Stay Discharge questionnaire. This shows very high levels of agreement.

**(2) PERSON/QUESTIONNAIRE LEVEL**

Table 2a2.3.c shows the CoreQ: Short Stay Discharge questionnaire items, and the agreement in response per item and responses for both the pilot survey of 853 patients compared with the re-administered survey of 100 patients. The person-level responses in the pilot survey are not statistically

significant from the re- administered survey. This shows that a high percent of time there was agreement between whether or not the pilot response was poor, average, good, very good or excellent, and whether or not the re- administered response was poor, average, good, very good or excellent. Table 2a2.3.d shows the average percent agreement between the pilot and re- administered responses In summary, 98% or more of the re- administered responses agreed with their corresponding pilot responses, in terms of whether or not they were rated in the categories of poor or average or good, very good or excellent.

**(3) MEASURE (FACILITY) LEVEL**

After having performed the 10,000-repetition bootstrap, 17.82% of bootstrap repetition scores were within 1 percentage point of the score under the original pilot sample, 38.14% were within 3 percentage points, 61.05% were within 5 percentage points, and 87.05% were within 10 percentage points.

**Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?**

Yes

**If yes, specify the number of cases and the percentage of providers**

20 and a 30% minimum response rate, 100% met this

**Type of Validity Testing**

Measure Score Validity; Data Element Validity

**Validity Testing: Type of Validity Testing Analysis**

Correlation; Face Validity; Construct Validity; Gold Standard Comparison; Internal Consistency; Predictive Validity; Structural Validity

**Validity Testing Sample Size**

In the development of the CoreQ: Short Stay Discharge questionnaire, four sources of data were used to perform three levels of validity testing. Each is described further below. The first source of data (convenience sampling) was used in developing and choosing the format to be utilized in the CoreQ: Short Stay Discharge questionnaire (i.e., response scale). The second source of data was pilot data collected from 865 patients (described below). This data was used in choosing the items to be used in the CoreQ: Short Stay Discharge questionnaire. The third source of data (collected from 285 facilities described in Section 1.5) was used to examine the validity of the CoreQ: Short Stay Discharge measure (i.e., facility and summary score validity).

**Validity Testing Statistical Result**

1. Validity Testing for the Questionnaire Format used in the CoreQ: Short Stay Discharge Questionnaire
    A. The literature review shows that domains used in the Pilot CoreQ: Short Stay Discharge questionnaire items have a high degree of both face validity and content validity.
    B. Patients overall rankings, show the general “domain” areas used indicates a high degree of both face validity and content validity.
    C. The results show that 100% of residents are able to complete the response format used.
    D. The Flesch-Kinkaid scale score was 6 or lower for all the questions.
2. Testing the Items for the CoreQ: Short Stay Discharge Questionnaire
    A. The percent of missing responses for the items is very low. The distribution of the

summary score is wide. This is important for quality improvement purposes, as nursing facilities can use benchmarks.

B. EFA shows that one factor explains the common variance of the items. A single factor can be interpreted as the only "concept" being measured by those variables. This means that the instrument measures the global concept of satisfaction and not multiple areas of satisfaction. This supports the validity of the CoreQ instrument as measuring a single concept of "customer satisfaction". This testing indicates a high degree of criterion validity.

C. The four questions used in the questionnaire were ranked by patients in the top 5 of importance out of 22 domains. The face validity of the response scale was also examined using multiple common scales for satisfaction. Whether patients understood how the response scale worked, could answer using the response scale and in cognitive testing understood the response scale. Flesche Kincaid score of 6 or lower is achieved with all questions.

3. Determine if a Sub-Set of Items Could Reliably be Used to Produce an Overall Indicator of Satisfaction (The Core Q: Short Stay Discharge Measure) - construct validity
    A. Correlation Coefficients of the highest 7 sets of correlations ranged from 0.818 to 0.841. In addition, using all items in the instrument a factor analysis was conducted using the global items Q1 ("How satisfied are you with the facility?") the Cronbach's Alpha of adding the "best" additional item. Chronbach's alpha measures the internal consistency of the values entered into the factor analysis, where a value of 0.7 or higher is generally considered acceptably high. The additional item(s) is considered best in the sense that it is most highly correlated with the existing item, and therefore provides little additional information about the same construct. So this analysis was also used to eliminate items. Note, the table again provides 7 sets of correlations, the analysis was conducted examining all possible correlations between items.
    B. Using all items in the instruments (excluding the global item Q1 ("How would you rate the facility?")) exploratory factor analysis (EFA) was used to evaluate the construct validity of the measure. The Eigenvalues from the principal factors (unrotated) are presented. Sensitivity analyses using principal factors and rotating provide highly similar findings. Factor 1 Eigenvalues 9.61, Factor 2 Eigenvalues = 0.37.
4. Validity Testing for the Core Q: Short Stay Discharge Measure.
    A. The correlation of the 4 item CoreQ: Short Stay Discharge measure summary score with the overall satisfaction score (scored using all data and the same scoring metric) gave a value of 0.94.

1. B.
2. (i)Relationship with CASPER Quality Indicators
3. The CASPER quality indicators that correlate with the CoreQ Short Stay Discharge score are any deficiency citations (-0.11; p=0.07), pressure ulcers (-0.22, p<0.01) and antidepressants (+0.13, p=0.03); those that do not correlate are physical restraints (-0.01, p=0.91), catheterization (-0.04, p=0.56), antipsychotic medications (-0.06, p=0.32), antianxiety medications (0.08, p=0.19), and hypnotic medications (0.04, p=0.46). This testing indicates a moderate degree of construct validity and convergent validity.
4. (ii)Relationship with Nursing Home Compare (NHC) Quality Indicators, Five Star ratings and staffing levels. These correlations range from ± 0.120 to 0.330. The CoreQ: Short-Stay Discharge measure is associated with these quality indicators, and always in the hypothesized direction

(good correlates with good). In particular, as emphasized in the structure-process-outcome framework of the evidence section, the link between staffing and customer satisfaction is particularly high, as confirmed by the correlation coefficients 0.330 for RN hours per resident-day and 0.305 for total staffing hours per resident day. This testing indicates a high degree of construct validity and convergent validity.

5. (iii) Relationship with the risk-adjusted Discharge to Community Measure
6. The risk-adjusted Discharge to community measure was negatively correlated to the CoreQ: Short Stay Discharge measure. The correlations were small ranging from -0.05 to -0.16.
7. (iv) Relationship with the risk adjusted PointRight® Pro 30™ Rehospitalizations
8. The risk-adjusted PointRight® Pro 30™ Rehospitalizations was negatively correlated to the CoreQ: Short Stay Discharge measure. The correlations were modest ranging from -0.22 to -0.31, and all of them were statistically significant at the p-value of 0.05.

### Validity Testing Interpretation of Results

1. Validity Testing for the Questionnaire Format used in the CoreQ: Short Stay Discharge Questionnaire
    A. The literature review shows that domains used in the Pilot CoreQ: Short Stay Discharge questionnaire items have a high degree of both face validity and content validity.
    B. Patients overall rankings, show the general “domain” areas used indicates a high degree of both face validity and content validity.
    C. The results show that 100% of residents are able to complete the response format used. This testing indicates a high degree of both face validity and content validity.
    D. The Flesch-Kinkaid scale score achieved for all questions indicates that respondents have a high degree of understanding of the items.
2. Testing the Items for the CoreQ: Short Stay Discharge Questionnaire
    A. The percent of missing responses for the items is very low. The distribution of the summary score is wide. This is important for quality improvement purposes, as nursing facilities can use benchmarks.

B. EFA shows that one factor explains the common variance of the items. A single factor can be interpreted as the only “concept” being measured by those variables. This means that the instrument measures the global concept of satisfaction and not multiple areas of satisfaction. This supports the validity of the CoreQ instrument as measuring a single concept of “customer satisfaction”. This testing indicates a high degree of criterion validity.

3. Determine if a Sub-Set of Items Could Reliably be Used to Produce an Overall Indicator of Satisfaction (The Core Q: Short Stay Discharge Measure).

A. Using the correlation information of the Core Q: Short Stay Discharge questionnaire (22 items) and the 4 items representing the CoreQ: Short Stay Discharge questionnaire a high degree of correlation was identified. This testing indicates a high degree of criterion validity. The additional item(s) is considered best in the sense that it is most highly correlated with the existing item, and therefore provides little additional information about the same construct. So this analysis was also used to eliminate items.

B. EFA shows that one factor explains the common variance of the items. A single factor can be interpreted as the only “concept” being measured by those variables. This means that the instrument measures the global concept of satisfaction and not multiple areas of satisfaction. This supports the validity of the CoreQ instrument as measuring a single concept of “customer satisfaction”. This testing

indicates a high degree of criterion validity.

4. Validity Testing for the Core Q: Short Stay Discharge Measure.

A. The correlation score between actual the “CoreQ: Short Stay Discharge Measure” and all of the 22 items used in the Pilot instrument indicates that the satisfaction information is approximately the same if we had included either the 4 items or the 22 item Pilot questions. This indicates that the CoreQ: Short Stay Discharge instrument summary score adequately represents the overall satisfaction of the facility. This testing indicates a high degree of criterion validity.

(i) Relationship with CASPER Quality Indicators

The 8 CASPER quality indicators had a low to moderate level of negative correlation with the CoreQ: Short Stay Discharge measure. Those that correlate have a clear conceptual link with short stay, and those that do not are more associated with long stay residents or have unclear conceptual links to short stay customer satisfaction. This testing indicates a moderate degree of construct validity and convergent validity.

(ii) Relationship with Nursing Home Compare (NHC) Quality Indicators, Five Star ratings and staffing levels

The Nursing Home Compare (NHC) Quality Indicators, Five Star ratings, and staffing levels all had a moderately high levels of correlation and in the direction predicted with the CoreQ: Short-Stay Discharge measure. The CoreQ: Short-Stay Discharge measure is associated with these quality indicators, and always in the hypothesized direction (good correlates with good). In particular, as emphasized in the structure-process-outcome framework of the evidence section, the link between staffing and customer satisfaction is particularly high, as confirmed by the correlation coefficients for RN hours per resident-day and for total staffing hours per resident day. This testing indicates a high degree of construct validity and convergent validity.

(iii) Relationship with the risk-adjusted Discharge to Community Measure

The risk-adjusted Discharge to community measure was negatively correlated to the CoreQ: Short Stay Discharge measure. The correlations were not as hypothesized which may be related to some SNFs that specialize in long stay, have very low discharge to community rates as admissions do not have a plan to go home.

(iv) Relationship with the risk adjusted PointRight® Pro 30™ Rehospitalizations

The risk-adjusted PointRight® Pro 30™ Rehospitalizations was negatively correlated to the CoreQ: Short Stay Discharge measure. This was expected because lower rehospitalization rates (an indicator of high quality) are associated with higher satisfaction. This was as hypothesized. This testing indicates a reasonable degree of construct validity and convergent validity.

As noted by Mor and associates (2003, p.41) “there is only a low level of correlation among the various measures of quality.” Castle and Ferguson (2010) also show the pattern of findings of quality indicators in nursing facilities is consistently moderate with respect to the correlations identified. Thus, it is not surprising that “very high” levels of correlations were not identified. Nevertheless, some correlation was identified.

**Measure performance – Type of Score**
Other: Percentage

**Measure Performance Score Interpretation**
Higher score is better

**Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have**
Max = 100, Minimum 25, Mean 82.5

**Benchmark, if applicable**
N/A

*Measure Contact Information*

**Measure Steward**
American Health Care Association/National Center for Assisted Living (AHCA/NCAL)

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## Section 2: Preliminary Analysis – MUC2021-095 CoreQ: Shot Stay Discharge Measure

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

**Yes/No:** Yes

**Justification and Notes:** There are no measures addressing patient experience currently in the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program. This NQF endorsed measure is one of five CoreQ measures. All are NQF endorsed, are utilized nationally, and have been adopted in some states for value-based purchasing and assisted living satisfaction reporting. Per the Consolidate Appropriations Act 2021, up to nine additional measures may be added to the SNF VBP Program including measures related to patient experience. The COVID-19 Public Health Emergency (PHE) has brought about even more discussion about nursing home experience and satisfaction.

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

**Yes/No:** Yes

**Justification and Notes:** The most recent year for available data was 2016 and it was estimated there were 606,800 short-stay nursing home patients in the U.S. (Centers for Disease Control and Prevention). As the U.S. population has aged and increased over the years, the estimates have most likely increased. This is a patient-reported outcome (PRO) measure. The developer's most recent spring 2020 CDP cycle submission cites numerous evidence indicating structure and process interventions within Skilled Nursing Facilities (SNFs) that ultimately result in patient discharge satisfaction.

**Does the measure address a quality challenge?**

**Yes/No:** Yes

**Justification and Notes:** This measure was originally considered for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) in 2017, the MAP supported this measure for rulemaking, but it was not part of the final rule making. The developer's spring 2020 CDP cycle submission included updated evidence. Data provided by Long Term Care Trend Tracker, included nursing home data covering 2016 Q1 to 2019 Q4. The mean satisfaction rates fluctuated between 77 to 80 percent with standard deviations from 14 to 19 percent. There is a range of variation in the performance with this measure within SNFs which will allow these facilities the opportunity to implement interventions and processes to improve 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:** There are no measures addressing patient experience in the SNF VBP Program. CMS' Meaningful Measures 2.0 initiative indicates person-centered care as a priority to build value-based care. Furthermore, CMS indicates prioritizing outcome and patient reported measures is a way to build towards this care.

**Can the measure be feasibly reported?**

**Yes/No:** Yes

**Justification and Notes:** The developer indicates all data elements are in defined fields in electronic

clinical data, for example clinical registry, nursing home minimum data set (MDS), or home health outcome and assessment information set. The measure is a four-question survey that can be added to an existing satisfaction survey or conducted independently.

**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 NQF endorsed measure is specified and tested at the facility level of analysis with nursing homes as the care setting. The target population is all short-stay, less than 100 days, patients regardless of payer status. Reliability testing indicated a high degree of element-level, questionnaire-level, and facility-level reliability. The questionnaire format testing indicated a high degree of both face and content validity. The items/responses testing indicated a high degree of criterion validity. Correlation between the measure and the pilot instrument represented overall satisfaction; this testing indicated a high degree of criterion 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:** N/A

**Justification and Notes:** The measure is not currently in use. The developer indicates there are no unintended consequences. However, the developer does recognize in some cases the questionnaire could highlight poor care for some dissatisfied residents which could cause further dissatisfaction. Public comments in the federal register regarding expansion of the SNF VBP program and potential addition of this measure resulted in mixed reviews. There were a few supportive comments, but also a concern that this measure would not fully reflect the patient experience (Centers for Medicare & Medicaid Services, 2021). Public comments from to 2020 CDP submission were similar; the comments also included intended use, the relationship with the Consumer Assessment of Healthcare Providers and Systems (CAHPS) measures, as well as concerns with exclusions and testing of the CoreQ scoring.

**PAC/LTC Core Concept?**
**Yes/No:** Yes

**Justification:** This measure meets one of the 13 PAC/LTC core concepts, Experience of Care. The concept reflects the overarching theme of patient engagement

**Impact Act Domain**
**Yes/No:** No

**Justification:** This measure does not meet one of the 8 Impact Act domains. Experience of care, patient engagement, and patient satisfaction are not one of the addressed domains.

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

**Justification:** N/A

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

- The Advisory Group generally agreed with the importance of this measure and relevance to rural providers and care settings

**Data collection issues:**

- None

**Calculation issues:**

- None

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 3.9
1 – 0 votes
2 – 0 votes
3 – 4 votes
4 – 10 votes
5 – 2 votes

### MAP Health Equity Advisory Group Input:

**Relative priority/utility:**

- The Advisory Group noted the importance of this person-centered measure
- The Advisory Group cautioned language differences that may result in response bias by race, ethnicity, language and by payer. The developer should also consider the increased response time and the role of care givers required for certain subpopulations.
- The Advisory Group also cautioned that certain subpopulations may be discharged to another facility due to payer and may be excluded from the measure.

**Data collection issues:**

- There are racial/ethnic dispirits in nursing home quality; an Advisory Group member would like to see more subgroup analyses and differences in satisfaction across subpopulations
- There is question of response bias, especially with language barriers or the exclusions with respect to caregivers
- The response time may also be a concern

**Calculation issues:**

- None

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 3.0
1 – 0 votes
2 – 7 votes
3 – 9 votes
4 – 8 votes
5 – 0 votes

*Recommendation*

**Preliminary Analysis Recommendation:**

Support for Rulemaking

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

This measure adds value to the SNF VBP Program set by adding a measure not currently addressed within the program, and this measure aligns with other PAC/LTC programs by working towards CMS' Meaningful Measures 2.0 overarching goal of value-based care. Per the Consolidated Appropriations Act of 2021, expansion of the measure set will add measures including those measuring patient experience. There is a range of variation in the performance with this measure within SNFs which will allow these facilities the opportunity to implement interventions and processes to improve performance.

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

In the year 2016 it was estimated there were 606,800 short-stay nursing home patients in the U.S. (Centers for Disease Control and Prevention). As the U.S. population has aged and increased over the years, the estimates have most likely increased. Nursing home data covering 2016 Q1 to 2019 Q4 indicated mean satisfaction rates fluctuated between 77 to 80 percent. The ongoing COVID-19 PHE has brought about even more attention on nursing home patient satisfaction. Person centered care, patient experience, and patient satisfaction are a focus of the healthcare community; improvement in those focus areas can help to improve the care for patients.

## Section 3: Public Comments

**Brown University School of Public Health**

I write in strong support of the use of the CoreQ Short-Stay Discharge Measure in the Medicare SNF VBP program. I currently direct the Center for Long-Term Care Quality & Innovation, a Brown University School of Public Health research center that conducts pragmatic research to measure and improve the quality of care for older adults receiving post-acute and long-term care. Previously (2008-2014), I led Rhode Island's public reporting program, which included requiring that nursing homes collect and report satisfaction data. I am therefore very familiar with public reporting, the existing quality metrics, and the nursing home setting. Because nursing homes are the only healthcare setting in which Medicare does not measure and report patient or resident satisfaction, there is a pressing need for the SNF VBP program to incorporate such a measure. While critics may argue that patient or resident experience may also be valuable, in addition to satisfaction, there are currently no valid or reliable experience measures for this setting. CoreQ, on the other hand, is ready and is ideal: it is based on four simple questions, has been validated, and is already endorsed by NQF. Additionally, it is one of the only measures that requires a minimum number of responses and a minimum response rate. I strongly endorse its use.

**LeadingAge**

LeadingAge supports the use of the CoreQ Short-Stay Discharge Measure for the SNF Value-Based Purchasing (VBP) program. This is the only publicly available, NQF-endorsed satisfaction measure for SNF Short-Stay residents that is widely used. We like that the CoreQ is a short survey with just 4 questions, which reduces the burden on residents and their family, and allows organizations to benchmark their results with consistent questions and a comparable response scale. While these questions don't identify granular level issues that a resident may have (e.g. a particular nurse they didn't

like or complaints about food quality), it asks key questions requiring the individual to assess their overall impressions of the nursing home, the staff who cared for them, the care received and their transition home. This is ultimately what consumers want to know. It reflects an overall impression of quality vs. discontent with one or two issues. It allows the individual to weigh all considerations in answering the questions. We understand CoreQ is already being used in multiple state VBP programs and over 30 customer satisfaction vendors have adopted it into their surveys. Use of this measure for the national SNF VBP program would provide alignment among these programs.

As for the measure calculation, we appreciate that it is limited to those with a post-acute admission and a length of stay of 100 days or less. We think the exclusions are appropriate. While we are supportive of this being an all-payer measure, we would be interested to see if the responses are dramatically different between those patients in Medicare fee-for-service and those who are part of a Medicare Advantage or Special Needs Plan. If there is a marked difference, CMS may want to consider comparing nursing homes with similar percentages of these populations, as otherwise, the results might be skewed. We have observed that care delivery expectations and patterns can vary greatly between the two payers with managed care plans limiting skilled days, and discharging at different functional levels. Consumers and their families are often not happy about these limits or being discharged before they feel they are ready. While patient satisfaction should be the same across payers, we would be concerned that they might negatively view the SNF based upon those plan decisions. For this reason, it would be good to bifurcate or analyze the data by payer source to determine if there is a difference in satisfaction that may be influenced by decisions made by a payer source. Another concern is it is not clear how this data will be collected. Will the burden be on the nursing home to conduct the survey or will there be a third-party who conducts the questionnaire and ensures unbiased results? If this is an additional task for the nursing home, we would ask that the measure be deferred until after the pandemic and/or public health emergency.

**Pinnacle Quality Insight**

Pinnacle Quality Insight conducts customer and employee satisfaction surveys for Long Term and Post-Acute Care providers. Pinnacle is an approved vendor for HHCAHPS and Hospice CAHPS surveys. Pinnacle also conducts CoreQ surveys for Nursing Homes. Pinnacle also conducts proprietary surveys for SNFs, ALFs, and ILFs.

A standardized Customer Satisfaction (CSAT) measurement for Nursing Homes is long overdue. The GAO recommended CMS add a satisfaction component to the five-star rating five years ago (https://www.gao.gov/products/gao-17-61). Nursing Homes are the only sector of care providers who accept Medicare dollars, who do not have a standardized CSAT tool.

A standardized CSAT measure allows CMS to add the data to Nursing Home Compare which is important for the public, but also allows each provider a benchmark of their performance. Publicly reported CSAT measures will improve patient outcomes and the patient experience in Nursing Homes by improving accountability and visibility.

It is our opinion that CoreQ Short Stay Discharge Measure is a better choice for the standard CSAT measurement than the NH CAHPS tool.

The primary reason being its elegant simplicity.

One of the challenges with CAHPS surveys are their length. They can be a burden to the respondent, and

they prohibit the care provider from conducting their own patient satisfaction surveys. The CoreQ tool has been proven to measure the most important areas of satisfaction while being brief and allowing the provider to ask additional questions for their own quality improvement if necessary.

Customer sentiment is very important in our economy, but it is typically measured very quickly. Many sectors measure customer satisfaction by using a Net Promoter Score (NPS) which comes from just one satisfaction question (How likely are you to recommend [product] to others?). Most of us are now very familiar with a short five-point scale customer satisfaction score (Amazon, Google, Yelp, etc.)

Shorter surveys are also less expensive to conduct, which is a lighter burden on the care provider.

The shorter CoreQ survey is pleasant for respondents, easier for care providers to implement and to understand, and still collects the most important data for stake holders.

Shorter surveys can also be added to an existing satisfaction instrument. This will allow providers to measure overall satisfaction through CoreQ and drill down into additional satisfaction domains of their choosing according to their unique care offering. There is no need for a standardized tool that measures anything other than overall satisfaction.

Frankly, long satisfaction surveys are outdated. Customers do not like them.

We have conducted CoreQ discharge surveys via web survey, phone survey and mailed postcard. We would highly recommend that all three modalities be approved.

We would also recommend that the rating scale be reviewed and validated again before becoming a part of the SNF QRP.

The rating scale for the CoreQ questionnaire is called a five-point Likert item. Likert items are useful because they can be summed together to make a Likert scale, like the CoreQ Short Stay Discharge Measure does.

However, well-designed Likert items have symmetry. Meaning the ""neutral' or ""average"" response is in the middle with an equal number of negative and positive responses along with it. (e.g. very bad, bad, average, good, very good)

They also have balance. Meaning the negative and positive responses are the mirror images of each other (e.g. very bad vs. very good.)

The CoreQ survey scale doesn't have balance or symmetry. In the five point CoreQ scale, the option ""average"" is the second option with one negative option (poor) and three positive options (good, very good, excellent). The top box scores are ""very good"" and ""excellent,"" it has been our finding so far that respondents have a hard time differentiating between what is ""very good"" and what is ""excellent.""

There is likely a reason this choice was made, and perhaps it doesn't affect the measure, but it is our recommendation that the rating scale be evaluated and validated before adoption.

However, these considerations are minor. It is our opinion that the CoreQ Short Stay Discharge Survey be adopted into the SNF QRP as the standard CSAT tool for Skilled Nursing Facilities. Our overall experience with CoreQ has been a lot more successful for providers and a lot more pleasant for

respondents than the CAHPS surveys.

### Health Care Association of New Jersey

The Health Care Association of New Jersey, which represents nursing homes and assisted living communities in the state of New Jersey, supports the use of the CoreQ Short-Stay Discharge Measure for the SNF VBP program. This measure is currently in use in our states Nursing Facility Quality Incentive Payment Program which is a value based purchasing program for SNF's. This is the only publicly available, NQF-endorsed satisfaction measure for SNF Short-Stay residents that is already widely used. The providers in our state greatly benefit from collecting customer satisfaction rates and the VBP program provides the incentive for them to utilize this standardized measure. This helps them track and trend data over time and incorporate customer satisfaction into their overall quality improvement efforts.

### GHCA

The Georgia Health Care Association represents nursing homes and assisted living communities in the state of Georgia. We are writing today in support of incorporating the CoreQ Short-Stay Discharge Measure in CMS' SNF VBP program. Satisfaction is currently in use in our state's Medicaid Quality Incentive Program. This is an important measure for our state and its providers, as it allows individual customer satisfaction vendors use their own satisfaction instruments while providing measures that can be comparable for our Medicaid payment purposes. This is also vital for providers who strive to use this data for quality improvement purposes, as it allows them to compare themselves to other providers in our state.

### Activated Insights

Hello:

This year we are surveying over 500,000 older adult residents and family members in over 4,000 senior care providers using the CoreQ questions this year.
The CoreQ questions and survey is easy. We add 25 additional questions to it, and the average time to complete the full survey is 9.5 minutes per our tracking of over 250,000 completed surveys.
In addition, I wanted to share some quotes from residents and providers in support of the CoreQ instrument:
** "This survey is a great idea" - Sheila G, Birmingham AL, age 78
** "Most of our nursing homes are in rural Texas and I like that the questions are so easy to understand" - Cassie, CEO of Senior Living Properties
** "I can't live without it - I see exactly how I'm doing and how it compares to others with the benchmarks" - Divisional VP, National Senior Living Provider based out of Florida
** "I enjoyed providing feedback and would be happy to do this regularly. Thank you for asking!!! And thanks for caring for my mom." - Adult daughter of a resident, University City, MD, mom is 82 years old.

### qbluesurveys

I believe that there would be great value in collecting the satisfaction measure. The burden on the resident and family is minimal and the data obtained would be a good indication of the level of quality care provided by the facility. Implementation is easy; data collection and submission is easy as well. data collected is beneficial to quality improvement efforts, since patient experience is a strong indicator, and since CoreQ is a validated tool, the data obtained is likely an accurate indication of satisfaction.

**NRC Health**

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

NRC believes that measuring the resident and family experience is an important piece of understanding the quality of care provided in a long term senior living environment. Experience data is more relatable to consumers than clinical quality measures. Consumers expect that providers have excellent clinical care, but they also need to ensure that they or loved ones will be treated as a person and have the highest quality of life possible when they need long term or rehab care. Having this information available to consumers as they make choices for themselves or their loved helps them to make fully informed decisions.

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

Our partners are collecting experience data because they see the benefit of having feedback from those they serve. Most all of them who are members of AHCA are choosing to add CoreQ to surveys they are already conducting. The burden of collecting this data is minimal.

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

NRC works with several Quality Incentive State Programs for long term skilled nursing centers who have adopted the CoreQ recommendation question as a measure to determine incentives for their Medicaid Programs. NRC has also worked with some states who have reported this data on a public web site, and one REIT who is using the CoreQ data as another measure of quality in their properties.

• Are there implementation challenges?

There are some challenges that NRC has encountered over the course of fielding the CoreQ question sets:

1. Response Rates – the required 30% RR is difficult for many of our clients to achieve, especially in the case of the short stay discharge survey which historically has been under 25%. The most recent published RR for short stay discharge is 21.2%.

2. Response Scale – using a 5-point scale has challenges in that all other questions on standard surveys use a 4 point scale. In decades of experience, we find that response scales with four options result in internally consistent patient responses. Question sets with 5 points require modification of standard reports to include a 3rd response. Most researchers use a top box, or top2 box positive score. With CoreQ NRC has adopted a top3 box positive score which has been challenging for some clients to utilize. In addition, the scale of Excellent, Very Good, Good, Average, Poor – lends itself to some confusion as Average is just above poor. The definition of average is the central or middle value in a data set. In these responses the middle response is good.

3. Response Scale - Switching response scales in the middle of a survey can be confusing for Seniors – NRC recommends that these questions fall at the end of a longer survey for this reason

4. Satisfaction based questions – The survey industry is moving away from satisfaction-based questions to loyalty and behavioral based questions. Behavioral based questions are different than traditional satisfaction questions. Asking residents or family to rate satisfaction asks the individual to use other knowledge or past experiences and to measure the most current experience against those previous

expectations. Behavioral based questions are used because they measure how often a behavior happens and gives the provider specific information on how to improve.

5. Redundancy - Would Recommend Question: NRC uses Net Promotor Score as a global measure of recommendation and loyalty. Using CoreQ adds redundancy to the survey with additional recommendation questions and increases the length of the survey. Longer surveys are shown to have lower response rates.

6. Composite Score – Providing composite scores to partners who use CoreQ requires custom reporting as it is not a standard measure in our reports. Composite scores are not easily understood by clients.

**American Hospital Association**

The AHA disagrees with the MAP's recommendation of Support for this measure and instead recommends a position of Conditional Support pending use in the SNF QRP prior to inclusion in the VBP program. This measure is currently only used as additional questions to the optional SNF CAHPS survey under a separate contract, so many of the mechanics of the survey's use are unclear. Specifically, it is unclear who will bear responsibility for transmittal, storage, and quality assurance of the data collected. We recommend that CMS determine the feasibility of implementing this question in a non-payment related program before tying performance on the measure to payments.

MUC2021-130 Discharge to Community-Post Acute Care Measure for Skilled Nursing Facilities (SNF)

## Section 1: Measure Information

*Measure Specifications and Endorsement Status*

**Program**
Skilled Nursing Facility Value-Based Purchasing Program

**Workgroup**
PAC/LTC

**Measure Description**
This measure estimates the risk-adjusted rate of successful discharge to community from a SNF, with successful discharge to community including no unplanned rehospitalizations and no death in the 31 days following SNF discharge. The measure is calculated using the following formula: (risk-adjusted numerator/risk-adjusted denominator)*national observed rate. The fields below describe the adjusted numerator and denominator in more detail. The measure is calculated using two years of Medicare FFS claims data.

**Numerator**
The measure numerator is the risk-adjusted predicted estimate of the number of residents who are discharged to the community, and do not have an unplanned readmission to an acute care hospital or LTCH in the 31-day post-discharge observation window, and who remain alive during the post-discharge observation window. This estimate starts with the observed (or unadjusted) number of discharges to community, defined as:

(i) discharges to home or self care with or without home health services, based on Patient Discharge Status Codes 01, 06, 81, or 86 on the Medicare FFS claim

(ii) no unplanned acute or LTCH hospitalizations in the 31-day post-discharge window

(iii) no death in the 31-day post-discharge window.

The discharge to community outcome is risk-adjusted for resident characteristics and a statistical estimate of the facility effect beyond case-mix (described below).

**Numerator Exceptions**
N/A

**Denominator**
The measure denominator is the risk-adjusted expected number of discharges to community. This estimate includes risk adjustment for resident characteristics with the facility effect removed. The "expected" number of discharges to community is the predicted number of risk-adjusted discharges to

community if the same residents were treated at the average facility. The denominator is computed in the same way as the numerator, but the facility effect is set at the average.

**Denominator Exclusions**

- Age under 18 years
- No short-term acute care hospital discharge within the thirty days preceding SNF admission
- Discharges to a psychiatric hospital
- Discharges against medical advice
- Discharges to disaster alternative care site or a federal hospital
- Discharges to court/law enforcement
- Discharges to hospice or resident stays with a hospice benefit in the 31-day post-discharge window
- Planned discharges to an acute or LTCH setting
- Stays for residents without continuous Part A FFS Medicare enrollment during the 12 months prior to the SNF admission date and the 31 days after the SNF discharge
- SNF stays preceded by a short-term acute care stay for non-surgical treatment of cancer
- Stays ending in transfer to a SNF
- Stays with problematic claims data (e.g. anomalous records for stays that overlap wholly or in part, or are otherwise erroneous or contradictory; claims not paid)
- Exhaustion of Medicare Part A benefit during the SNF stay
- SNF stays in facilities outside of the United States, Puerto Rico, or another U.S. territory
- Swing bed stays in critical access hospitals
- Having a nursing facility in the 180-day lookback window preceding the admission date of the prior proximal inpatient stay

**Denominator Exceptions**

N/A

**State of development**

Fully Developed

**State of Development Details**

Beta testing was conducted for this measure, including reportability, reliability, and validity testing. Overall, these tests demonstrated that the measure could be reported for a majority of facilities given the denominator threshold, and were found to be sufficiently reliable and valid. Please see the reliability and validity subsections for more detailed results.

**What is the target population of the measure?**

Medicare Fee for Service SNF beneficiaries.

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

Other: N/A

**Measure Type**

Outcome

**Is the measure a composite or component of a composite?**

No

**If Other, Please Specify**
N/A

**What data sources are used for the measure?**
Claims Data; Other: Assessment Data, specifically, the Minimum Data Set (MDS)

**If applicable, specify the data source**
N/A

**If EHR or Chart-Abstracted data, description of parts related to these sources**
The Discharge to Community-Post Acute Care Measure for Skilled Nursing Facilities (DTC-PAC SNF) is based on Medicare fee-for service (FFS) administrative claims and uses data in the Medicare enrollment and claims files. The enrollment files provide information such as date of birth, date of death, sex, reasons for Medicare eligibility, periods of Part A coverage, and periods in the Medicare FFS program. The data elements from the Medicare FFS claims are those basic to the operation of the Medicare payment systems and include data such as date of admission, date of discharge, diagnoses, and procedures The claims data files contain stay-level post-acute care (PAC) and hospital records. No data beyond the bills submitted in the normal course of business are required from providers for the calculation of this measure.

**At what level of analysis was the measure tested?**
Facility; Other: Stay

**In which setting was this measure tested?**
Skilled nursing facility

**What one healthcare domain applies to this measure?**
Safety

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

**CMIT ID**
2846

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Endorsed

**NQF ID Number**
NQF #3481

**If endorsed: Is the measure being submitted exactly as endorsed by NQF?**
No

**If not exactly as endorsed, specify the locations of the differences**
Exclusions

**If not exactly as endorsed, describe the nature of the differences**
Through the rulemaking process, CMS received input from stakeholders voicing concerns about SNF

patients who were nursing home residents at baseline (i.e. prior to their index stay), and were therefore much less likely to be discharged to the community. Analyses of FY 2017 data showed that a relatively small proportion of eligible stays (about 10.4%) were excluded, and the resulting performance rates remained very similar in terms of relative rates and relative ranks. Rank and rate correlations between the measure before and after this exclusion were both 0.97. As a result, baseline nursing home residents were excluded from the measure calculation.

**If endorsed: Year of most recent CDP endorsement**
2019

**Year of next anticipated NQF Consensus Development Process (CDP) endorsement review**
2022

**Submitter Comments**
N/A

### *Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

### *Measure Use in CMS Programs*

**Was this measure proposed on a previous year's Measures Under Consideration list?**
Yes

**Previous Measure Information**
Year: 2015

Measure ID: MUC15-462

Workgroup: Post-Acute Care\/Long-Term Care

Program: SNF QRP

Recommendation: Encouraged Continued Development

Not Recommended: MAP noted that available discharge codes and coding practices could cause confusion about the results of this measure and could also introduce validity concerns. MAP asked for greater clarity about the intent of these measures, especially how they may impact patients and consumers. MAP members raised concerns about the multiple ways that readmissions are being measured and noted that a provider could potentially be penalized multiple times for the same occurrence. MAP noted the need for excluding patients who are admitted to hospice to prevent discouraging discharges to hospice. MAP also noted that discharge to community can reflect access to social support and the measure may need to reflect this. MAP indicated the need for these measures to be submitted for NQF review and endorsement to address psychometric concerns about the measures.MAP members noted concerns about the risk adjustment of these measures, particularly for the home health setting. MAP specifically noted the need to appropriately risk adjust the measures to avoid unintended consequences.

Report Page Number: MAP 2016 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care (page 5)

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

**Range of years this measure has been used by CMS Programs**
Skilled Nursing Facility (SNF) Quality Reporting Program (2017-present)

**What other federal programs are currently using this measure?**
Skilled Nursing Facility Quality Reporting Program

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

**Which measure(s) already in a program is your measure similar to and/or competing with?**
N/A

**How will this measure be distinguished from other similar and/or competing measures?**
N/A

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

**If this measure is being proposed to meet a statutory requirement, please list the corresponding statute**
The Consolidated Appropriations Act, 2021

## *Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**
See Evidence Form in the MIFForm_3481.zip attachment

### Evidence that the measure can be operationalized

This measure is based on Medicare claims, which CMS uses for provider payments and a wide variety of other measures. Assessment data (used for exclusions) are also already collected by CMS for use in measures and other purposes. This measure was adopted in the SNF QRP in FY 2018 and subsequent years. Annual public reporting of this measure on Nursing Home Compare began in October 2018. Data for this measure may be found on the Care Compare website (https://www.medicare.gov/care-compare/) and the Provider Data Catalog (https://data.cms.gov/provider-data/).

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

Claims;Other: Assessment Data, specifically, the Minimum Data Set (MDS)

### Feasibility of Data Elements

ALL data elements are in defined fields in administrative claims;ALL data elements are in defined fields in electronic clinical data (e.g., clinical registry, nursing home minimum data set, or MDS, home health Outcome and Assessment Information Set, or OASIS)

### Evidence of Performance Gap

An analysis of FY 2018-2019 SNF claims indicates that there is a performance gap in DTC rates across SNFs. Among 15,103 SNFs included in the 2018-2019 sample, risk-adjusted measure scores ranged from 7.11% (min) to 84.70% (max) with a mean score of 52.55% and a standard deviation of 11.02%. The 25th percentile, median, and 75th percentile were 45.01%, 52.88%, and 60.54%, respectively.

### Unintended Consequences

No unexpected findings have been noted during implementation of this measure. No unintended impacts on residents have been detected to date during the course of CMS monitoring.

### Outline the clinical guidelines supporting this measure

N/A

### Were the guidelines graded?

N/A

### If yes, who graded the guidelines?

N/A

### If yes, what was the grade?

N/A

### Estimated Impact of the Measure: Estimate of Annual Denominator Size

In FY 2018-2019, performance scores were calculated for 15,103 SNFs with 2,783,909 SNF eligible stays.

### Estimate of Annual Improvement in Measure Score

In FY 2018-2019, an additional 149,560 discharge to community outcomes could have been achieved if all SNFs performing below the national mean score had instead achieved at least the mean score.

### Type of Evidence to Support the Measure

Systematic Review; Empirical data

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

Risk adjusted

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

**Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event**
Unable to determine

**Cost Avoided Annually by Medicare/Provider**
Unable to determine

**Source of Estimate**
None

**Year of Cost Literature Cited**
None

*Patient and Provider Perspective*

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

**If yes, choose all methods of obtaining patient/caregiver information**
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives;Other: Public Comment Periods for pre-rulemaking and rulemaking

**How many times and at what phase(s) of measure development was the patient/caregiver engaged?**
A representative was engaged during each of the three TEP meetings during measure development. Measure implementation involved public comment periods associated with pre-rulemaking, rulemaking, and NQF endorsement.

**Total Number of Patients and/or Caregivers Consulted**
1

**Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups**
1:16

**Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions**
1

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

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

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

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

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

**If yes, choose all methods that obtained clinician and/or provider input**
Standard TEP;Other: Public Comment periods for pre-rulemaking and rulemaking

**Total Number of Clinicians/Providers Consulted**
12

**Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care**
12

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

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

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

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

**Does the measure require manual abstraction?**
No

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

**How many data elements will be collected for the measure?**
N/A. This measure requires no additional data submission beyond what is already collected on Medicare FFS claims in the normal course of business.

## *Measure Testing Details*

**Reliability Testing Interpretation of Results**
The ICC for the overall SNF sample was 0.88, indicating good reliability. Further, this result likely represents an underestimation due to reliability calculations conducted on half the data in the measurement period, a consequence of dividing each facility's resident stays within this measure period into halves in the testing approach.

**Type of Reliability Testing**
Measure Score Reliability

**Reliability Testing: Type of Testing Analysis**
Random Split Half Correlation

**Reliability Testing Sample Size**
The sample for reliability testing included 13,344 SNFs that had 25 or more resident stays in the FY 2018-

2019 measurement period.

**Reliability Testing Statistical Result**

Split-sample Reliability Testing: This testing examined agreement between two performance measure scores for a facility based on randomly-split, independent subsets of resident stays in the same measurement period. We randomly divided each facility's FY 2018-2019 resident stays into halves. We calculated performance measure scores for each split-half sample using the same measure specification. We calculated Shrout-Fleiss intraclass correlation coefficients ((ICC (2, 1) and ICC (3, 1)) between the split-half scores to measure reliability [1].

The split-sample reliability testing for both ICC (2, 1) and ICC (3, 1) were 0.88 when the split samples are drawn with replacement. When the split samples are drawn without replacement – i.e. for each provider, the observations are divided into two mutually exclusive halves - we use two alternative methods to correct for the artificial reduction in sample size. The Spearman-Brown correction yields ICCs of 0.86 (under appropriate assumptions) and imposing a case minimum of 25 in each split sample yields ICCs of 0.78. All approaches are demonstrating good reliability.

[1] McGraw, K. O., & Wong, S. P. (1996). Forming inferences about some intraclass correlation coefficients. Psychological methods, 1(1), 30.

**Reliability testing Interpretation of Results**

The ICC for the overall SNF sample was 0.88, indicating good reliability. Further, this result likely represents an underestimation due to reliability calculations conducted on half the data in the measurement period, a consequence of dividing each facility's resident stays within this measure period into halves in the testing approach.

**Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?**

Yes

**If yes, specify the number of cases and the percentage of providers**

The minimum number of denominator cases was 25, which was met by 13,344 providers, or 88.4% of all SNFs (n= 15,103) in the test sample.

**Type of Validity Testing**

Measure Score Validity;Data Element Validity

**Validity Testing: Type of Validity Testing Analysis**

Correlation; Face Validity; Predictive Validity

**Validity Testing Sample Size**

Given that the discharge status code on SNF claims is a key component of the numerator criteria, a validity test was performed to ensure high levels of accuracy for this data element. The test assessed if discharge status locations were consistent between SNF claims and MDS discharge assessments. This testing included 2,413,451 index SNF stays that were successfully matched to MDS assessments. The MDS discharge to community definition was based on MDS item A2100 (Discharge Status) with values of 01-Community (private home/apt., board/care, assisted living, group home) being classified as discharge to a community setting. We then examined the percentage of matched stays where the discharge status matched between these sources using a dichotomous criterion of discharged to community vs. not discharged to community.

Empirical validity testing for the performance measure score was conducted through correlation analyses of measure scores. DTC measure scores were compared to those of eight other measures (i.e., SNF Potentially Preventable Readmission Post Discharge (PPR-PD), Medicare Spending Per Beneficiary (MSPB), Percentage of short-stay residents who got antipsychotic medication for the first time, Percentage of short-stay residents who needed and got a flu shot for the current flu season, Percentage of short-stay residents who needed and got a vaccine to prevent pneumonia, Percentage of short-stay residents who improved in their ability to move around on their own, Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients, and Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients). The subset of SNFs from the FY 2018-2019 data included in each of these analyses was restricted to those with available data for both measures, and the size of the subsets ranged from 12,696 to 14,717 SNFs.

Face validity testing was conducted through a convening of three TEPs, an environmental scan, and public comment.

### Validity Testing Statistical Result

Of the 2,413,451 index SNF stays matched to MDS assessments, the dichotomous discharge status criteria noted above matched on 93.5% of the stays.

DTC measure scores were negatively associated with scores of the SNF PPR-PD measure, MSPB measure, and short-stay quality measure of Percentage of short-stay residents who got antipsychotic medication for the first time, which assesses negative outcomes.

DTC measure scores were positively associated with scores of short-stay measures assessing positive outcomes (i.e., Percentage of short-stay residents who needed and got a flu shot for the current flu season, Percentage of short-stay residents who needed and got a vaccine to prevent pneumonia, and Percentage of short-stay residents who improved in their ability to move around on their own, and functional outcome measures (i.e., Application of IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients and Application of IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients).

Most correlation coefficients were small (absolute values ranged from 0.04 to 0.39), indicating that the DTC measure is associated with other measures in the expected direction, but it is not duplicative and provides unique information about quality of care not captured by other measures. Of the eight correlations assessed, all were statistically significant at the 0.05 level.

We analyzed the model fit statistics to determine if the risk model can accurately predict DTC while controlling for differences in resident case-mix. The C-statistic of the model was 0.72.

We found extensive support for the face validity and importance of the DTC measure as an indicator of quality of care based on our environmental scan, TEP feedback, and public comment feedback. For the face validity testing, all (17) members of the TEP voted in favor of the measure score's face validity.

### Validity Testing Interpretation of Results

The 93.5% match rate of the dichotomous discharge status between SNF claims and MDS discharge assessments indicates SNF claims appropriately indicate an individual resident's discharge status.

DTC measure scores also correlate with other measure scores as expected, but not so much that the information captured by the measure is duplicative.

The C-statistic of the risk model was 0.72 which suggests good model discrimination.

As stated in item 035, we found extensive support for the face validity and importance of the DTC measure as an indicator of quality of care based on our environmental scan, TEP feedback, and public comment feedback.

**Measure performance – Type of Score**
Proportion

**Measure Performance Score Interpretation**
Higher score is better

**Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have**
Mean performance rate (from risk-standardized performance scores): 52.55%

Standard Deviation: 11.02 percentage points

**Benchmark, if applicable**
Not Applicable

*Measure Contact Information*

**Measure Steward**
Centers for Medicare and Medicaid Services

**Measure Steward Contact Information**
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202-205-2913

**Long-Term Measure Steward**
N/A

**Long-Term Measure Steward Contact Information**
N/A

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## Section 2: Preliminary Analysis – MUC2021-130 Discharge to Community – Post Acute Care Measure for Skilled Nursing 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 measures addressing successful discharge to community currently in the Skilled Nursing Facility Value Based Purchasing (SNF VBP) Program. This is a NQF endorsed measure currently utilized in the Skilled Nursing Facility Quality Reporting Program (SNF QRF) and a similar measure (NQF #3480) is utilized in the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). Per the Consolidated Appropriations Act 2021, up to nine additional measures may be added to the SNF VBP Program including those measures related to functional status and care coordination.

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

**Justification and Notes:** This measure is an outcome measure. The developer's evidence submitted during the fall 2018 CDP cycle indicated improvement in successful discharge to community rates among PAC patients is possible through modifying provider-led processes and interventions within the PAC setting. The developer cites evidence noting the interventions that enhance discharge transitions have been associated with improved discharge to community rates and reduced readmission rates following community discharge.

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

**Justification and Notes:** The measure was originally developed to address the measure domain of discharge to community mandated by the Improving Medicare Post-Acute Care Transformation Act (IMPACT Act) of 2014 (Centers for Medicare & Medicaid Services, 2014). The developer noted performance gap in the discharge to community rates across SNFs. The 2018-2019 risk-adjusted measure scores ranged from 7.11 percent to 84.70 percent with a mean risk-adjusted score of 52.55

percent. There is variation in the performance of this measure within SNFs and these facilities will have the ability to implement interventions to improve 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:** There are no measures addressing successful discharge to community currently in the SNF VBP Program. CMS' Quality Measurement Action Plan not only addresses building value-based care with Meaningful Measures 2.0 including care coordination, but it also addresses the goals to achieve this care (Centers for Medicare & Medicaid Services, 2021). This measure addresses several of these goals including measures focused on key quality domains, align measures across programs, prioritize outcome measures, and implement measures that reflect social and economic determinants.

**Can the measure be feasibly reported?**

**Yes/No:** Yes

**Justification and Notes:** The developer indicates all data elements are captured in defined fields in administrative claims already collected and no additional data will be required from providers. Specifically, the assessment data will be captured in the Minimum Data Set (MDS).

**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 NQF endorsed measure is specified and originally tested at the facility level of analysis with skilled nursing facilities as the care setting. During the rulemaking process, CMS received input from stakeholders voicing concerns regarding SNF patients who were nursing home residents at baseline and thus less likely to be discharged to the community. The target population for this measure is the same as the endorsed measure, Medicare Fee for Service SNF beneficiaries, but excludes baseline nursing home residents for the calculation. The developer conducted a split half reliability test. The intra-class correlation was 0.88, indicating good reliability. Two validity tests (empirical and face validity) were performed; the claims data accurately indicated a discharge to community compared to authoritative sources. Three technical expert panels (TEPs) were conducted and resulted in support for the face 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:** This measure is currently utilized in the SNF QRF and a similar measure is utilized in the LTCH QRP. No unexpected findings have been noted and no negative unintended issues to patients have been identified. Two comments from the 2018 CDP endorsement cycle expressed concerns over the lack of inclusion of dual eligible status in the risk-adjustment model. In response, the developer stratified the measure and did not find a difference in outcomes; the correlations were high.

**PAC/LTC Core Concept?**

**Yes/No:** Yes

**Justification:** This measure meets one of the 13 PAC/LTC core concepts, Transition Planning. The

concept Transition Planning consists of discharge planning and timely and bi-directional communication during transitions. Successful transitions require educating and preparing patients and patients' families/caregivers, as well as timely communication between the sending and receiving clinicians/ institutions.

### Impact Act Domain

**Yes/No:** Yes

**Justification:** This measure meets one of the eight domains within the IMPACT Act of 2014, Discharge to Community. The Act requires the development and reporting of measures pertaining to several domains, including discharge to community.

### Hospice High Priority Areas

**Yes/No:** N/A

**Justification:** N/A

### MAP Rural Health Advisory Group Input:

**Relative priority/utility:**

- The Advisory Group generally agreed with the importance of this measure and relevance to rural providers and care settings.

**Data collection issues:**

- None

**Calculation issues:**

- None

**Unintended consequences:**

- Advisory Group members raised concerns about distance rural patients may have to travel from SNFs to community-based settings. Noting that this distance may create negative unintended consequences. The developer did clarify that in testing rural providers generally performed better on this measure compared to the general population, but would monitor for this concern.

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 3.9
1 – 0 votes
2 – 1 votes
3 – 1 votes
4 – 14 votes
5 – 1 votes

### MAP Health Equity Advisory Group Input:

**Relative priority/utility:**

- The Advisory Group noted that there may be differences in the availability of community resources upon discharge from SNFs; as the measure may be sensitive to food insecurity and housing instability
- The Advisory Group acknowledged that dual eligibility is included in risk adjustment model but encouraged stratification of the measure

- The Advisory Group agreed that nursing home residents should excluded since they are less likely to be discharged to the community but cautioned that each of the exclusions should be examined from an equity lens. It is important that the quality of care for patients who are discharged to law enforcement, psychiatric facilities, or other subpopulations is examined as well.

**Data collection issues:**

- None

**Calculation issues:**

- Discussion on the impact of the drivers of health outcomes. Stratification of the measure was done within nursing homes by dual status, as this measure if very susceptible to patient characteristics.
- The Advisory Group questions whether the AHRQ SES Index was tested or any social risk indicator beyond dual eligibility. The developer stated that there was early SES testing, such as race and ethnicity.
- Concern about nursing home patients may not be likely to be discharged to the community and would this skew the measure in any way. The developer clarified that those that are baseline nursing home patients are excluded, as they will most likely be discharged back to the nursing home rather than the community
- Risk adjustment can highlight differences, but the measures should NOT adjust away differences; stratification is important here

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 2.9
1 – 0 votes
2 – 11 votes
3 – 5 votes
4 – 8 votes
5 – 0 votes

### *Recommendation*

**Preliminary Analysis Recommendation:**

Support for Rulemaking

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

This measure adds value to the SNF VBP program set by adding a measure not currently addressed within the program, and this measure aligns with other PAC/LTC programs utilizing the same measure. The measure aligns with CMS' Quality Measurement Action Plan to build value-based care by addressing several goals including measures focused on key quality domains, aligning measures across programs, prioritizing outcome measures, and implementing measures that reflect social and economic determinants.

**Summary: What is the potential impact of this measure on quality of care for patients?**
The empirical evidence demonstrates improvement in successful discharge to community rates among PAC patients is possible through modifying provider-led processes and interventions within the PAC setting. With the continuing COVID-19 public health emergency, the desire and potential need for successful discharges may be necessary to ease healthcare facility burden. The 2018-2019 risk-adjusted measure scores ranged from 7.11 percent to 84.70 percent with a mean risk-adjusted score of 52.55 percent. There is variation in the performance of this measure within SNFs and these facilities will have the ability to implement interventions to improve performance and care for patients.

## Section 3: Public Comments

### AHCA

This measure is NQF endorsed, already in use and is aligned with the VBP program goals to determine if Medicare part A payments are achieving greater value and rewarding SNF providers that provide better outcomes. It complements the other measure (30 day rehospitalization) already in use.

### LeadingAge

This measure represents a clear goal for short-stay residents to return to the community. It has been previously reported under the SNF QRP program so providers are familiar with the reporting structure. Overall, we support the inclusion of this measure and its application to short-stay residents in the SNF. However, we are concerned about the exclusion of Medicare Advantage and/or Special Needs Plan enrollees from the denominator. In some U.S. counties with MA/SNP enrollment can exceed 50 - 60%, which will result in few eligible stays for these nursing homes., It will be important for CMS to address, how it will approach low volume situations for this measure. Will they be excluded from their VBP score making other measures more heavily weighted? With a smaller denominator, just a few cases where individuals aren't discharged to the community can skew a SNF's performance and create an unfair comparison with other SNFs. We would also like to better understand the resident characteristics that will be used to risk adjust for this measure (e.g. co-morbidities, age, dual eligible status, socio-economic status, prior hospitalizations, etc.). In addition, we note that individuals who were previously receiving custodial nursing home care are not excluded from this measure. We would hope that individuals that return to their long-stay nursing home are also considered a discharge back to the community as opposed to conversion to long-stay care. We hope this would be remedied prior to implementation.

### Johnson & Johnson

Johnson & Johnson agrees with the Workgroup's recommendation to support the measure for rulemaking. Johnson & Johnson supports measures that promote well-managed care transitions and standardization of clinical activities that can be shared with providers to improve transitions.

Rehabilitation interventions, discharge planning, and care coordination can improve discharge to community rates. Thus, evidence from other inpatient PAC/LTC and hospital settings can be used to support this measure. Discharge to community is an actionable health care outcome, as targeted interventions have been shown to successfully increase discharge to community rates in a variety of post-acute settings and hospital settings. We would encourage inclusion of activities such as relevant guideline concordant vaccinations as part of the discharge planning, to promote patient outcomes, safety and reduce readmissions.

### American Hospital Association

The AHA agrees with the MAP's recommendation of Support for this measure. The measure is endorsed by NQF and has been used—and revised to improve accuracy—in the SNF and other post-acute quality reporting programs for multiple years. The measure is a useful indicator of outcomes that are of interest to patients.

## MUC2021-124 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization

# Section 1: Measure Information

### *Measure Specifications and Endorsement Status*

**Program**
Skilled Nursing Facility Value-Based Purchasing Program

**Workgroup**
PAC/LTC

**Measure Description**
This measure estimates the risk-adjusted rate of healthcare-associated infections (HAIs) that are acquired during skilled nursing facility (SNF) care and result in hospitalizations. The measure is risk adjusted to "level the playing field" and to allow comparison of performance based on residents with similar characteristics between SNFs. The one-year measure is calculated using the following formula: (risk-adjusted numerator/risk-adjusted denominator)*national observed rate. It is important to recognize that HAIs in SNFs are not considered "never-events." The goal of this risk-adjusted measure is to identify SNFs that have notably higher rates of HAIs when compared to their peers.

**Numerator**
To calculate the measure numerator, we first count the outcome and then apply risk-adjustment. The final measure numerator is the adjusted numerator.

Measure Outcome - Unadjusted

The unadjusted numerator is the number of stays with an HAI acquired during SNF care and resulting in an inpatient hospitalization. The hospitalization must occur during the period beginning on day 4 after SNF admission and within 3 days after SNF discharge. HAIs are identified using both the principal diagnosis code and the Present on Admission (POA) indicator on the re-hospitalization claim.

Measure Outcome - Adjusted

The final numerator is a risk-adjusted estimate of the number of SNF stays predicted to have an HAI that results in hospitalization. This estimate starts with the observed (i.e. unadjusted) count of the measure outcome, which is then risk adjusted for resident characteristics and a statistical estimate of the measured SNF's effect beyond resident case mix. The SNF effect accounts for clustering of patients within the same facility and captures variation in the measure outcome across SNFs, which helps isolate the differences in measure performance that are due to provider-specific behavior and characteristics.

**Numerator Exceptions**
The measure only includes HAIs reported on inpatient claims. Emergency department visits and observation stays are excluded from the numerator.

An HAI is excluded from the numerator if it is a pre-existing infection. A pre-existing infection is defined as an HAI that was reported in any of the diagnosis code fields on the most proximal hospitalization claim prior to the SNF admission with a discharge date that is less than 14 days from the admission date of the readmitting inpatient (IP) stay. The pre-existing infection recorded in the prior proximal hospitalization must be a diagnosis that is related to the HAI recorded in the re-hospitalization.

The definition of HAI excludes the following infection types:

- chronic infections (e.g. subacute and chronic melioidosis)
- infections that typically require a long period of time to present (e.g. typhoid arthritis)
- infections that are likely related to the prior hospital stay (e.g. postprocedural retroperitoneal abscess)
- infections likely to be community acquired (e.g. echinococcus granulosus infection of liver)
- infections common in other countries and/or acquired through animal contact (e.g. subacute and chronic melioidosis)

The definition of HAI also excludes the following types of diagnosis codes:

- codes likely to represent secondary infection, where the primary infection would likely already be coded (e.g. viral endocarditis infections likely to be community acquired
- codes that include “causing disease classified elsewhere” (e.g. meningitis in bacterial diseases classified elsewhere)
- sequela and subsequent encounter codes (e.g. sequelae of inflammatory diseases of central nervous system)

### Denominator

To calculate the measure denominator, we first count the number of eligible stays and then apply risk-adjustment. The final measure denominator is the adjusted denominator.

Unadjusted Denominator:

Part A FFS Medicare SNF stays during the measurement period.

Adjusted Denominator:

The measure denominator is the risk-adjusted “expected” number of SNF stays with the measure outcome. The calculation of the “expected” number of stays starts with the total eligible SNF stays which is then risk adjusted for resident characteristics excluding the SNF effect. The “expected” number of stays with the measure outcome represents the predicted number of stays with the measure outcome if the same SNF residents were treated in the “average” SNF.

### Denominator Exclusions

SNF stays are excluded from the denominator if they meet one or more of the following criteria:

- Resident is under 18 years old at SNF admission
- Resident is not continuously enrolled in Part A FFS Medicare during the measurement period (1 year before SNF admission and 3 days after discharge)
- SNF length of stay was shorter than 4 days
- SNF stay cannot be matched to prior inpatient stay within 30 days before SNF admission

- Resident was transferred to federal hospital
- SNF stay has zero Medicare payment
- Provider of stay is outside of the 50 U.S. states, Puerto Rico, or U.S. Territory
- SNF stay does not have complete information for measure construction and risk adjustment

### Denominator Exceptions
N/A

### State of development
Fully Developed

### State of Development Details
We briefly summarize testing results here, and further details are in the appropriate areas of the form below.

Reportability Testing:

We examined the total number and proportion of SNFs that would have at least 25 eligible stays for this measure using one year of data. In FY 2019, 84.90% of total SNFs (n= 14,102) met this threshold. This indicates high reportability and usability of the measure.

Variability Testing:

We summarized the distribution of the facility-level risk standardized HAI rate. In FY 2019, the mean risk-adjusted HAI rate among SNFs with at least 25 eligible stays was 5.84% (median: 5.85%, IQR: 4.75%-6.69%). The risk-adjusted HAI rate among reportable SNFs ranged from a minimum of 2.36% to a maximum of 17.62%.

**Reliability Testing:**

1. We conducted split-half testing to assess the internal consistency of the measure. The average correlation from the 20 iterations was 0.50, which suggests moderate reliability.
1. Validity Testing:
1. We analyzed the model fit statistics to determine if the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix. The C-statistic of the model was 0.72, which suggests good model discrimination.
2. To assess convergent validity, we assessed the relationship between the HAI measure and other related publicly reported quality measures including Discharge to Community (DTC), Potentially Preventable 30-Day Post-Discharge Readmission Measure (PPR), Percentage of short-stay residents who were assessed and appropriately given the seasonal influenza vaccine, Percentage of short-stay residents assessed and appropriately given the pneumococcal vaccine, and the Five-Star RN Staffing measure. The correlations were in the expected direction and all Spearman's rank correlations were statistically significant using the alpha level of 0.05.
3. We convened a Technical Expert Panel (TEP) meeting in May 2019 to assess the face validity of this measure. TEP members supported the conceptual and operational definition of the HAI measure and agreed with the measure specifications.
4. We performed a correlation analysis between HAI rates and COVID-10 case rates, as well as HAI rates and COVID-19 death rates. The correlations were in the expected direction and all Spearman's rank correlations were statistically significant using the alpha level of 0.05.

**What is the target population of the measure?**
Medicare FFS SNF beneficiaries

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

**Measure Type**
Outcome

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

**If Other, Please Specify**
N/A

**What data sources are used for the measure?**
Claims Data

**If applicable, specify the data source**
N/A

**If EHR or Chart-Abstracted data, description of parts related to these sources**
The SNF HAI measures is based on Medicare fee-for service (FFS) administrative claims and uses data in the Medicare enrollment and SNF and IP claims files. The enrollment files provide information such as date of birth, date of death, sex, reasons for Medicare eligibility, periods of Part A coverage, and periods in the Medicare FFS program. The data elements from the Medicare FFS claims are those basic to the operation of the Medicare payment systems and include data such as date of admission, date of discharge, diagnoses, procedures, and indicators for use of dialysis services and intensive care and coronary care services. The claims data files contain stay-level post-acute care (PAC) and hospital records. No data beyond the bills submitted in the normal course of business are required from providers for the calculation of this measure.

**At what level of analysis was the measure tested?**
Facility; Other: Stay

**In which setting was this measure tested?**
Skilled nursing facility

**What one healthcare domain applies to this measure?**
Safety

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

**CMIT ID**
N/A

**Alternate Measure ID**
CMS ID S005.02

**What is the endorsement status of the measure?**
Never Submitted

**NQF ID Number**
N/A

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

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

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

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

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

**Submitter Comments**
N/A

*Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

*Measure Use in CMS Programs*

**Was this measure proposed on a previous year's Measures Under Consideration list?**
Yes

**Previous Measure Information**
Year: 2020

Measure ID: MUC20-0002

Workgroups: Rural Health Workgroup, 2020; Post-Acute Care/Long-Term Care Workgroup, 2020; Coordinating Committee, 2020

Programs: Skilled Nursing Facility Quality Reporting Program, 2020

Recommendation: Conditionally Support, 2020

Not Recommended: N/A

Report Page Number: Measure Applications Partnership 2020-2021 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital & PAC/LTC, page 22

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

**Range of years this measure has been used by CMS Programs**
Skilled Nursing Facilities Quality Reporting Program (2022)

**What other federal programs are currently using this measure?**
Skilled Nursing Facility Quality Reporting Program

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

**Which measure(s) already in a program is your measure similar to and/or competing with?**
Related measures included in CMS PAC Quality Reporting Programs and Nursing Home Quality Initiative Program:

- NQF #0684 Percent of Residents with a Urinary Tract Infection (Long-Stay) (NQF #0684)
- NQF #0138: National Healthcare Safety Network Catheter-associated Urinary Tract Infections (CAUTI)
- NQF #0139: National Healthcare Safety Network Central Line-Associated Bloodstream Infections (CLABSI)
- NQF #1717: National Healthcare Safety Network Facility-Wide Inpatient Hospital-onset Clostridium difficile Infection Outcome Measure
- Skilled Nursing Facility 30-Day Potentially Preventable Readmission after Hospital Discharge measure (SNFPPR)
- Skilled Nursing Facility 30-Day All-Cause Readmission measure (SNFRM) (NQF #2510)
- Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting
- Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for Skilled Nursing Facility Quality Reporting

**How will this measure be distinguished from other similar and/or competing measures?**
None of these measures (NQF #0684, 0138, 1039, 1716, 1717, 2510, or the SNFPPR) directly compete with the SNF HAI measure as they are either not specific to the SNF population (apply similar methodology across PAC settings), only capture one type of infection rather than HAIs overall, or do not incorporate an indicator for infection severity.

This SNF HAI measure will be implemented in SNF QRP which focuses on reporting of quality measures.

It does not directly compete with the SNF VBP as SNF VBP rewards SNFs with incentive payments based on measure performance.

**How will this measure add value to the CMS program?**

The intent of this measure is to assess all HAIs acquired in SNFs that result in hospitalizations, a concept that is not currently assessed in the SNF VBP program and that was not previously included in the SNF QRP. The SNF VBP program has no infection control measures. Further, previously existing infection measures in the SNF QRP were not specific to SNF residents and were aimed at measuring specific types of infections (i.e. those associated with the use of specific devices, specific locations, or specific bacterial organisms) rather than HAIs overall. Additionally, there were no measures that focus on infections requiring hospitalization, a criterion that can be used to assess the severity of infections and providers' management of infections. In terms of hospitalizations, the existing readmission measures for the SNF setting (SNFRM and SNFPPR) are not focused on infections. Rather, they cover hospitalizations due to several reasons such as inadequate management of chronic conditions, infections, inadequate injury prevention and inadequate management of other unplanned events. Unlike the HAI measure, the existing SNF readmission measures include readmissions due to infection without accounting for pre-existing or repeated infections.

Therefore, the added benefit of this proposed HAI measure is that it focuses on severe infections and captures several infection types in the SNF setting. This measure will generate actionable data on infection rates that can be used to target quality improvement in the highest impact areas.

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

The Consolidated Appropriations Act, 2021

## *Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**

Healthcare associated infection (HAI) is defined as an infection acquired while receiving care at a health care facility that was not present or incubating at the time of admission. [1] If the prevention and treatment of HAIs are poorly managed, they can cause poor health care outcomes for patients and lead to wasteful resource use. Most HAIs are considered potentially preventable because they are outcomes of care related to processes or structures of care. In other words, these infections typically result from inadequate management of patients following a medical intervention, such as surgery or device implantation, or poor adherence to hygiene protocol and antibiotic stewardship guidelines. Measuring HAIs among SNF residents can therefore provide valuable information about SNFs' quality of care.

HAIs are associated with longer lengths of stay, use of higher-intensity care (e.g., critical care services and hospital readmissions), and increased mortality. [2, 3, 4] HAIs also lead to increased health care costs and present an economic burden. [2,5] Addressing HAIs in SNFs is particularly important because several factors place SNF residents at high risk for infection, including increased age, cognitive and functional decline, use of indwelling devices, frequent care transitions, and close contact with other residents and health care workers. [6,7] A recent report from the Office of Inspector General (OIG, 2014) estimated that 1 in 4 adverse events among SNF residents are due to HAIs and that more than half of all HAIs are potentially preventable. [2] Infection prevention and control programs with core components in education, monitoring, and feedback on infection rates from surveillance programs or feedback on

infection control practices from audits have been found to be successful interventions for reducing HAIs. [8]

Preventing and reducing HAIs is crucial to delivering safe and high-quality care across the health care system and has been a priority objective at the federal, state, and local levels. For example, the Office of Disease Prevention and Health Promotion has created a National Action Plan to Prevent Health Care-Associated Infections, with specific attention to HAIs in long-term care facilities (LTCFs). [6] In 2017, CMS launched the Meaningful Measures framework. “Making Care Safer by Reducing Harm Caused in the Delivery of Care” is one of the six meaningful measure domains and is a companion priority for quality assurance and improvement work at CMS. The meaningful measure area of HAIs is under this domain.

**References:**


1. World Health Organization. (n.d.). The burden of health care-associated infection worldwide. Retrieved from https://www.who.int/gpsc/country_work/burden_hcai/en/
2. Office of Inspector General. (2014). Adverse events in skilled nursing facilities: National incidence among Medicare beneficiaries. Retrieved from https://oig.hhs.gov/oei/reports/oei-06-11-00370.pdf
3. Ouslander, J. G., Diaz, S., Hain, D., & Tappen, R. (2011). Frequency and diagnoses associated with 7- and 30-day readmission of skilled nursing facility patients to a nonteaching community hospital. Journal of the American Medical Directors Association, 12(3), 195–203. http://dx.doi.org/10.1016/j.jamda.2010.02.015Zimlichman et al., 2013
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7. Montoya, A., & Mody, L. (2011). Common infections in nursing homes: A review of current issues and challenges. Aging Health, 7(6), 889–899. http://dx.doi.org/10.2217/ahe.11.80
8. Lee, M.H., Lee GA, Lee SH, Park YH (2019). Effectiveness and core components of infection prevention and control programmes in long-term care facilities: a systematic review. Retrieved from https://pubmed.ncbi.nlm.nih.gov/30794854/


### Evidence that the measure can be operationalized

The data needed to calculate this measure are readily available and require no additional data submission beyond what is already collected on Medicare FFS claims in the normal course of business. This measure poses no additional data collection burden to SNF providers.

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

Claims

### Feasibility of Data Elements

ALL data elements are in defined fields in administrative claims

### Evidence of Performance Gap

This measure intends to identify SNF providers that have a significantly higher or lower HAI rate in comparison to the average SNF with the same resident population. An analysis of FY 2018 SNF claims indicates that there is a performance gap in HAI rates across SNFs. Among 14,347 SNFs included in the 2018 sample, risk-adjusted measure scores ranged from 2.19% (min) to 19.83% (max) with a mean score of 6.15% and a standard deviation of 1.72%. The 25th percentile, median, and 75th percentile were 4.91%, 5.85%, and 7.08%, respectively. For updated results on FY 2019 SNF claims, please refer to the State of Development, Reliability Testing, and Validity Testing sections of this form.

The literature review indicates that there is wide variation in HAI rates by provider characteristics across SNFs, indicating potential opportunities for some SNF providers to improve the quality of care they deliver. Past research shows that HAI rates are associated with staffing levels in nursing homes. For example, both urinary tract infections (UTIs) and multidrug resistant organisms (MDROs) rates were negatively related to the RN staff rating component of the Nursing Home Five-Star Quality Rating System [1]. Other literature found nursing facility structural characteristics and resident case mix impacted infection rates in both nursing homes and SNFs, including chain membership, occupancy rates, size and proportion of Medicare and Medicaid beneficiaries [2, 3]. Lastly, the adoption of infection surveillance and prevention policies in nursing homes is associated with facility characteristics such as profit status, chain status, hospital affiliation, size and percentage of Medicare residents [4].

**References:**


1. 1.Gucwa, A. L., Dolar, V., Ye, C., & Epstein, S. (2016). Correlations between quality ratings of skilled nursing facilities and multidrug-resistant urinary tract infections. American Journal of Infection Control, 44(11), 1256–1260. http://dx.doi.org/10.1016/j.ajic.2016.03.015
2. 2.Castle, N., Engberg, J. B., Wagner, L. M., & Handler, S. (2017). Resident and facility factors associated with the incidence of urinary tract infections identified in the Nursing Home Minimum Data Set. Journal of Applied Gerontology, 36(2), 173–194. http://dx.doi.org/10.1177/0733464815584666
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### Unintended Consequences

This measure may lead SNFs to selectively enroll residents, either by encouraging or avoiding admission of certain types of residents and residents with certain characteristics. The measure specification could incentivize very short SNF stays leading to inadequate care, since the measure excludes SNF stays shorter than 4 days.

To address these potential challenges, providers' performance is evaluated among their peers after adjusting for difference in resident case-mix across SNFs. The risk adjustment methodology applied to this measure will help mitigate providers' incentive to selectively enroll residents or transfer residents to hospitals early. The variables included in the risk adjustment model are designed to capture resident characteristics that are associated with higher rates of HAIs. Therefore, providers' performance on this

measure will be adjusted for the characteristics of their resident population and “level the playing field” across providers. The detailed risk-adjustment strategy is publicly available, allowing providers to understand that those who provide care for more “high risk” residents are not at a disadvantage given their resident case mix. The technical report for the SNF HAI measure is available at: https://www.cms.gov/files/document/snf-hai-technical-report.pdf. This measure will be monitored to identify unintended consequences, including patient selection patterns, which could lead to future re-specification of the measure as needed.

**Outline the clinical guidelines supporting this measure**
N/A

**Were the guidelines graded?**
N/A

**If yes, who graded the guidelines?**
N/A

**If yes, what was the grade?**
N/A

**Estimated Impact of the Measure: Estimate of Annual Denominator Size**
Approximately 14,000 SNFs. In FY 2019, 14,102 SNFs and 1,787,275 SNF stays were eligible for reporting of this measure.

**Estimate of Annual Improvement in Measure Score**
24,577 avoided HAIs

**Type of Evidence to Support the Measure**
Systematic Review;Empirical data

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

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

**Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event**
$14,948.01

**Cost Avoided Annually by Medicare/Provider**
$367,376,691.51

**Source of Estimate**
To estimate the average cost savings per event, we calculated the average total Medicare payment for an HAI readmission. We derived total Medicare payment from the inpatient claim for the HAI readmission.

To estimate the annual cost avoided by Medicare, we multiplied the average Medicare payment for HAI readmission by the estimated number of cases avoided.

These estimates rely on the assumption that the total Medicare payment reflects solely the cost of treating the HAI. We made this assumption because by definition, an HAI is identified using the principal diagnosis code on the inpatient claim. However, we acknowledge the inaccuracies resulting from this assumption as it is possible that part of the Medicare payment may also reflect routine services and treatment costs for other clinical conditions present during the hospitalization.

**Year of Cost Literature Cited**
All estimates are based on FY2019 FFS claims.

*Patient and Provider Perspective*

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

**If yes, choose all methods of obtaining patient/caregiver information**
Standard Technical Expert Panel (TEP) inclusive of patient/caregiver representatives

**How many times and at what phase(s) of measure development was the patient/caregiver engaged?**
Patient/caregivers were engaged one time during measure development. The TEP included a patient advocate/caregiver. This population was also engaged twice during measure implementation. The SNF HAI measure had two separate public comment periods during pre-rulemaking and rulemaking processes.

**Total Number of Patients and/or Caregivers Consulted**
1 TEP member followed by public comment periods

**Specify the ratio of patients/caregivers to policy/clinician experts engaged in TEP or working groups**
1:11

**Total number of patients/caregivers who agreed that the measure information helps inform care and make decisions**
We did not track this information.

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

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

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

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

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

**If yes, choose all methods that obtained clinician and/or provider input**
Standard TEP

**Total Number of Clinicians/Providers Consulted**
8 clinicians/providers on TEP, followed by public comment periods

**Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care**
N/A. We did not track this information.

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

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

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

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

**Does the measure require manual abstraction?**
No

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

**How many data elements will be collected for the measure?**
This measure requires no additional data submission beyond what is already collected on Medicare FFS claims in the normal course of business.

*Measure Testing Details*

**Reliability Testing Interpretation of Results**
The average correlation from the 20 iterations was 0.50, which suggests moderate reliability.

**Type of Reliability Testing**
Measure Score Reliability

**Reliability Testing: Type of Testing Analysis**
Random Split Half Correlation

**Reliability Testing Sample Size**
The sample for reliability testing included 14,338 facilities.

**Reliability Testing Statistical Result**
We conducted split-half testing to assess the internal consistency of the measure. In split-half testing, stays within a SNF are randomly assigned into two groups and the risk adjusted HAI rate per facility is calculated for both groups. To maintain the precision of the estimate as the measure would be used in the program, we doubled our sample size by including two years of data (FYs 2018 and 2019) prior to

splitting the sample into two groups. This process only included SNFs with at least 50 stays in FYs 2018 and 2019 and was repeated 20 times to rule out extreme values. We used Spearman's rank correlation to assess the correlation between the HAI rates of the two groups. The average correlation from the 20 iterations was 0.50.

**Reliability Testing: Was a minimum number of denominator cases per measured entity established to achieve sufficient measure score reliability?**

Yes

**If yes, specify the number of cases and the percentage of providers**

To be eligible for this one year measure, facilities must have at least 25 stays. In FY 2019, 84.90% of total SNFs (n= 14,102) met this threshold. The split-half testing included facilities with at least 50 stays over two years. Due to the splitting into two random groups, we doubled our sample size by including two years of data (FYs 2018 and 2019) and doubled the stay eligibility requirement to ensure at least 25 residents could be used in each randomly selected half of a facility's residents. This results in a reliability test sample of 14,338 SNFs (85.40% of total SNFs).

**Type of Validity Testing**

Measure Score Validity

**Validity Testing: Type of Validity Testing Analysis**

Correlation;Construct Validity;Predictive Validity

**Validity Testing Sample Size**

The validity testing sample included 16,615 facilities for model fit analysis and 13,589 facilities for the correlation analysis.

**Validity Testing Statistical Result**

1. We analyzed the model fit statistics to determine if the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix. The C-statistic of the model was 0.72.
2. To assess convergent validity, we assessed the relationship between the HAI measure and other publicly reported quality measures. The analysis was restricted to FY 2019 and only included data from providers with at least 25 stays. Using the Spearman's rank correlation, we compared the HAI measure to SNF QRP claims-based measures [Discharge to Community (DTC) and Potentially Preventable 30-Day Post-Discharge Readmission Measure (PPR)], NHQI short-stay assessment-based measures [Percentage of short-stay residents who were assessed and appropriately given the seasonal influenza vaccine and Percentage of short-stay residents assessed and appropriately given the pneumococcal vaccine], and Five-Star Quality Rating measures [RN Staffing]. As expected, the following measures were negatively correlated with HAI: DTC (-0.45), RN Staffing (-0.25), Percentage of short-stay residents who were assessed and appropriately given the seasonal influenza vaccine (-0.11), Percentage of short-stay residents assessed and appropriately given the pneumococcal vaccine (-0.09). As expected, PPR was positively correlated with HAI (0.12). All Spearman's rank correlations were statistically significant using the alpha level of 0.05.
3. We convened a Technical Expert Panel (TEP) meeting in May 2019 in which the TEP showed strong support for the face validity of the HAI measure, though a vote was not taken at the meeting. TEP members agreed with the conceptual and operational definition of the HAI measure. Specifically, the TEP agreed that the measure should focus on infections severe

enough to require hospitalization and supported the clinical criteria used to select HAI diagnoses.

4. We assessed the relationship between SNF HAI measure rates in FY2019 and COVID-19 spread in CY2020. In this analysis, we stratified SNFs into quintiles of HAI rates and calculated the average HAI rate, the percentage of facilities without COVID-19 cases, and average COVID-19 case and death rates for each quintile. Facilities in higher quintiles, with higher SNF HAI measure rates, had a higher average number of COVID-19 cases and deaths per 1,000 residents and had lower percentages of providers with no COVID-19 cases. Specifically, there was an average of 161.6 COVID-19 cases per 1,000 residents in the fifth quintile, compared to 90.5 in the first. There was an average of 30.4 COVID-19 deaths per 1,000 residents in the fifth quintile compared to 18.0 in the first. In the fifth quintile, 8.1% of providers had zero cases of COVID-19 compared to 14.6% in the first quintile. We also conducted rank-order correlations between the SNF HAI measure and COVID-19 metrics. SNF HAI measure rates are positively correlated with the number of COVID-19 cases ($r_s = 0.139$, $p < 0.0001$) and deaths ($r_s = 0.110$, $p < 0.0001$) per 1,000 residents.

**Validity Testing Interpretation of Results**

1. The C-statistic of the model was 0.72, which suggests good model discrimination.
2. The direction of the correlations aligned with clinical expectations and all Spearman's rank correlations were statistically significant using the alpha level of 0.05. This indicates good convergent/predictive validity and that the SNF HAI measure is closely related to other measures of similar construct.
3. TEP members supported the conceptual and operational definition of the HAI measure and agreed with the measure specifications. This suggests strong face validity and that SNF HAI measures what it intends to measure.
4. The quintile analysis shows that Medicare-certified nursing homes providing SNF care with higher SNF HAI measure rates in FY2019 have higher numbers of COVID-19 cases and deaths and are less likely to remain free of COVID-19. The correlations were in the expected direction and all Spearman's rank correlations were statistically significant using the alpha level of 0.05. Positive correlations between COVID-19 cases and deaths and SNF HAI measure rates reveals that facilities with higher SNF HAI measure rates are more likely to be impacted by COVID-19. Overall, this analysis demonstrates that the SNF HAI is closely related to other measures of infection control and management.

**Measure performance – Type of Score**

Proportion

**Measure Performance Score Interpretation**

Lower score is better

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

In FY 2019, the mean risk-adjusted HAI rate among SNFs with at least 25 stays was 5.84% and the standard deviation was 1.52%.

**Benchmark, if applicable**

N/A

*Measure Contact Information*

**Measure Steward**
Centers for Medicare & Medicaid Services

**Measure Steward Contact Information**
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**Long-Term Measure Steward**
N/A

**Long-Term Measure Steward Contact Information**
N/A

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## Section 2: Preliminary Analysis – MUC2021-124 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization

**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 measures addressing healthcare-associated infections (HAIs) currently in the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program. This is an existing measure, conditionally supported by MAP 2020, and recently adopted for use in the Skilled Nursing Facility Quality Reporting Program (SNF QRP). Per the Consolidated Appropriations Act 2021, up to nine

additional measures may be added to the SNF VBP Program including those related to patient safety.

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

**Justification and Notes:** The developer cites numerous evidence indicating the incidence of HAIs is associated with longer lengths of stay, higher intensity care needs, and increased mortality among skilled-nursing facility patients. A recently published study indicates U.S. hospitals saw significant increase in HAIs during 2020, resulting from the COVID-19 pandemic (Weiner-Lastinger et al., 2021). The developer reported validity testing in which SNF HAI rates positively correlated with the number of COVID-19 cases and deaths. The developer further cites evidence demonstrating basic infection prevention and control (IPC) measures can help to prevent HAIs.

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

**Justification and Notes:** The developer cites evidence indicating one in four adverse events among SNF patients is attributed to HAIs, more than half are potentially preventable. Patients within SNFs are at greater risk for infection due to increased age, functional decline, and close proximity to other patients and healthcare personnel. The developer reported data from 2019 indicates the mean risk adjusted HAI score was 5.84 percent with an interquartile range (IQR) of 4.75 percent to 6.69 percent. Data from 2018 indicates the mean risk-adjusted score was 6.15 percent.

**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 an all-cause readmission measure in the SNF VBP program, while this measure is specific to HAI hospitalizations. There are other infection specific measures in PAC/LTC programs, while none of them are specific to HAI hospitalization. Meaningful Measures 2.0 indicates safety as a continued focus of CMS in order to build value-based care (Centers for Medicare & Medicaid Services, 2021).

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

**Justification and Notes:** The developer indicates all data elements are captured in defined fields in administrative claims already collected and no additional data will be required from providers.

**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, conditionally supported by MAP 2020, is not currently NQF endorsed. This fully developed measure is specified and tested at the facility-level of analysis with skilled nursing facilities as the care setting. The target population is Medicare fee-for-service beneficiaries who do not meet the exclusion criteria and the measure was tested using claims data. The developer conducted a split half reliability test. The average correlation was 0.50, which indicates moderate reliability. All Spearman's rank correlations were statistically significant using the alpha level of 0.05, which indicates good convergent/predictive validity. The developer also convened a technical expert

panel (TEP) which showed strong support for the face validity of the HAI measure.

**If the measure is in current use, have negative unintended issues to the patient been identified? Have implementation challenges outweighing the benefits of the measure been identified?**
**Yes/No:** N/A

**Justification and Notes:** This measure was recently adopted for use within the SNF QRP. The developer noted this measure may lead SNFs to selectively enroll residents, either by encouraging or avoiding admission of certain types of residents or those with certain characteristics. The measure could also incentivize short SNF stays leading to inadequate care, since the measure excludes stays shorter than four days. The developer indicated the risk adjustment methodology applied to the measure will help mitigate providers' incentive to selectively enroll residents or transfer residents to hospitals early. CMS' request for public comment on potential measures in the SNF VBP program indicated a few supporters of this measure to prioritize improved patient outcomes.

**PAC/LTC Core Concept?**
**Yes/No:** Yes

**Justification:** This measure meets one of the eight core concepts. The concept, Infection Rates, is specifically defined in the MAP documentation as "including healthcare-associated infections (HAIs)."

**Impact Act Domain**
**Yes/No:** No

**Justification:** N/A

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

**Justification:** N/A

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

- The Advisory Group generally agreed with the importance of this measure and relevance to rural providers and care settings

**Data collection issues:**

- None

**Calculation issues:**

- An Advisory Group member noted concerns around small numbers for healthcare-associated infections, given the numerator modeling approach. The developer noted that the HAI-rate is generally stable, given the testing conducted.

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 3.9
1 – 0 votes

2 – 1 votes
3 – 3 votes
4 – 8 votes
5 – 4 votes

**MAP Health Equity Advisory Group Input:**

**Relative priority/utility**

- The Advisory Group noted that this measure is important but cautioned that the risk adjustment should be examined to ensure disparities are not made worse. Age and gender may pose equity challenges for this measure. The developer noted that observed and risk-adjusted rates are monitored for this reason

**Data collection issues:**

- None

**Calculation issues:**

- There was discussion on risk adjustment, in which there should be adjustment of factors that are outside of the providers control and caution to not to over adjust to lower the standard of what quality care should be across populations of social risk
- One way to address this concerns is to track improvement over time and evaluate how this measure is used; what is scoring well mean, is it improvement in its own scores over time or just compared against other SNFs

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 2.9
1 – 2 votes
2 – 6 votes
3 – 7 votes
4 – 5 votes
5 – 1 votes

## *Recommendation*

**Preliminary Analysis Recommendation:**

Conditional Support for Rulemaking, pending NQF endorsement.

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

This measure adds value to the SNF VBP program by adding an overall measurement of all HAIs acquired within SNFs requiring hospitalizations and was recently adopted within another PAC/LTC program. Meaningful Measures 2.0 indicates safety as a continued focus of CMS in order to build value-based care (Centers for Medicare & Medicaid Services, 2021). Infection control and prevention can aid in reducing HAIs within SNFs. There is variation in the performance of this measure within SNFs and these facilities will have the ability to implement interventions to improve performance.

**Summary: What is the potential impact of this measure on quality of care for patients?**
Patients within SNFs are at greater risk for infection due to increased age, functional decline, and close proximity to other patients and healthcare personnel. Evidence indicates one in four adverse events among SNF patients is attributed to HAIs, more than half are potentially preventable. Recent claims data indicates a risk adjusted HAI score from 2019 was 5.84 percent and 2018 was 6.15 percent. Moreover, a recently published study indicates U.S. hospitals saw significant increase in HAIs during 2020, resulting from the COVID-19 pandemic (Weiner-Lastinger et al., 2021). Education, monitoring, and feedback on infection rates can aid in reducing HAIs and improving care for patients.

The condition for Support for Rulemaking is for the measure to be submitted to NQF for endorsement.

## Section 3: Public Comments

**The Society for Healthcare Epidemiology of America**
The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to submit comments on the 2021-2022 Recommendations for Measures Under Consideration (MUC) list published on December 1, 2021. Our comments focus on the MUC2021-124 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization proposed measure.

SHEA represents more than 2,000 physicians and other healthcare professionals globally with expertise in healthcare epidemiology, infection prevention and antibiotic stewardship. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality and the cost of care linked to healthcare-associated infections (HAIs) and antibiotic resistance.

Thank you in advance for your consideration of our comments.
Sincerely,
Mary Hayden, MD, FIDSA, FSHEA
President
SHEA

MUC2021-124 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization
The list of measures for early public feedback includes MUC2021-124 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization measure (hereafter referred to as the "SNF HAI measure") for use in the Skilled Nursing Facility Value Based Program (SNF VBP).

After careful review of the HAI measure, SHEA does not support it and does not recommend its adoption into the SNF VBP. While SHEA unequivocally supports efforts to improve the quality of care delivered in the long-term care setting through the SNF VBP, SHEA continues to have concerns that the HAI measure as proposed will create a strong disincentive to transfer residents to acute care, adding even more to concerns about penalties and fines than currently exist.
Our concerns fall within several domains:

1) Accuracy of using ICD-10 codes;
2) Validity of coding on acute care hospital discharge;
3) Use of a composite score;

4) Preventability of the metrics used in the HAI composite score;
5) Incomplete culture data upon admission to SNFs that inappropriately attributes infection or colonization to the SNF;
6) Location of attribution; and
7) Incubation period for infections

Accuracy of using ICD-10 codes. The HAI measure identifies HAIs based on ICD-10 codes upon admission to the hospital. While it may seem that using ICD-10 codes in the long-term care (LTC) setting for quality measurement would be helpful in alleviating reporting burden, there have been many publications describing the inaccuracies of using administrative data to define HAIs. CMS should instead consider the revised McGeer criteria, which assess infections in LTC settings. CMS should also carefully consider using alternate thoughtfully developed definitions to assess infections in LTC settings that are grounded in evidence, agreed upon by experts, and already used in real-world settings.

Validity of coding on acute care hospital discharge. In addition to general concerns about the accuracy of using ICD-10 codes for surveillance, the HAI measure relies on an assumption that hospitals would correctly and accurately classify symptoms and diagnoses upon admission so that these data can be used to assess the quality of care delivered in the LTC setting. It also assumes patients being transferred from an acute care setting to a SNF are clinically stable at the time of discharge. Both assumptions do not bear out in practice.

Use of a composite score. The proposed HAI score includes heterogeneous types of infections, many of which are non-preventable. Using a composite score makes it difficult to target interventions toward prevention. For example, how will SNFs decide on a targeted intervention (e.g., hand hygiene, antibiotic stewardship, etc.) if the score is high without knowing which metrics are driving the overall score? Preventability of the metrics used in the HAI composite score. Many of the infections listed in the ICD-10 code are not related to management of the patients in the post-acute setting. Some examples include:

- Infection and inflammatory reaction due to other prosthetic device, implant and graft in urinary system, initial encounter. Infection and inflammatory reaction due to implanted penile prosthesis, initial encounter;
- Infection of amputation stump, unspecified extremity;
- Bronchiectasis with acute lower respiratory infection;
- Candidal sepsis;
- Community-associated infections such as meningococcal meningitis, salmonella, shigella, viral encephalitis, etc.; and
- Cellulitis

Incomplete culture data. Patients may be admitted to a SNF with incomplete culture data resulting in a diagnosis that inappropriately attributes infection or colonization to the SNF. Common examples of such instances are outlined below:

- Urinary tract infection, site not specified – In the case of urinary tract infections (UTI), many patients are admitted with UTI due to abnormal urinalysis and are likely to have asymptomatic bacteriuria. For example, if a resident falls, is sent to the hospital and while being evaluated for injury, a urinalysis finds the resident has an Extended Spectrum Beta-Lactamase (ESBL) in the urine. The ESBL is present on admission to the hospital, but is it considered an HAI from the SNF because a hospital provider may insist on treating the positive urine before they will proceed

with further treatment? Will the administrative data be able to identify this as asymptomatic bacteriuria?

- Sepsis – Many patients are originally diagnosed with "sepsis" but, upon further workup, have a non-infectious reason for their illness.
- Clostridioides difficile infection – The definition and timing for hospital-onset, SNF-onset and undetermined C. difficile infection has been the focus of much research. Even with this single pathogen that causes one clinical syndrome and which is readily detected by tests available to SNFs, there is a great deal of discussion about the attribution of the infection.

Location of attribution. It is also very difficult to determine which provider should be ascribed responsibility for an infection that occurs post discharge. For example: If a resident develops a wound at a hospital and comes to a SNF for care for that wound, which later becomes infected with a multi-drug resistant organism infection, should the infection be attributed to the hospital? Or the SNF? The hospital created the pre-existing condition and the SNF is the place where the wound was determined to be infected.
Incubation period for infections. The recommendation for including a four-day after SNF admission for determination of an HAI is not reflective of the clinical events involved with an HAI. The incubation period for some of the infections are longer than four days (e.g., Hepatitis B and C).

Conclusion
As an alternative to the HAI measure as proposed, SHEA continues to recommend consideration of a requirement like that implemented in select states where at least one person trained in infection control be available at the facility, with their hours predicated on the number of beds.
SHEA thanks NQF again for the opportunity to provide feedback on the MUC List. As we noted, we would be happy to provide NQF with any additional detail or address any questions you may have as you work to finalize the rule.

**AHCA**

While this measure addresses an important topic, this measure is NOT ready for inclusion in rule making for the SNF VBP program for following reasons: (1) it is not NQF endorsed and there is not statutory deadline that requires this measure be added urgently to the VBP program prior to seeking NQF endorsement. (2) this measure relies on hospital claims to determine the source of infection, which is notoriously flawed for determining UTIs and urosepsis, the two most common reasons along with pneumonia for triggering the numerator in this measure. The incorrect diagnosis of UTI and urosepsis are well documented and thus lead this measure to often incorrectly code an admission as a healthcare associated infection. (3) there is scant evidence to support that UTIs and urosepsis are preventable in long term care setting. This measure has the unintended effect to prevent transfers to the hospital for residents with acute infections needing treatment. this measure needs more development and testing and should be used in other programs before linking it to Medicare Part A payments.

**LeadingAge**

We like many aspects of how the measure is calculated but believe it would be premature to implement this as a SNF VBP measure impacting reimbursement when it hasn't been endorsed by NQF, has not been tracked before in a SNF and will not be added to SNF QRP until FY2023. The measure itself should be tested from a reporting standpoint first and endorsed by the National Quality Forum prior to adjusting SNF payment based upon performance on the measure. We also would like to better understand the rationale for how it was determined that the measure is initiated 4 days after SNF

admission vs. a different timeframe, and understand whether COVID-19 infections would be included if a resident required inpatient hospitalization. We also would like to understand what resident characteristics will be used to risk adjust this measure (e.g. socio-economic status, co-morbidities, age, prior hospitalizations in the past 12 months, etc.). We assume that this will be collected via MDS or claims data, if so we would anticipate low administrative burden. If, however, it requires a separate reporting structure, we would oppose based upon additional administrative burden. Essentially, we would like SNFs to have a chance to ensure adequate and accurate reporting before making this a VBP measure.

**Premier, Inc.**

While Premier conceptually supports this measure, we do not support adoption of this measure into the SNF VBP at this time. We continue to fully support efforts to reduce healthcare associated infections (HAIs), recognizing that many HAIs are potentially preventable and associated with longer lengths of stay, higher healthcare costs, use of higher-intensity care, and increased mortality. We urge CMS to take an incremental approach to implementing this measure and recommend that CMS continue to evaluate this measure as part of the QRP before adopting into the SNF VBP. This will allow providers to gain more experience with the measure before being held accountable for payment.

**American Health Care Association**

Not ready for rule making; its an aggregate measure of multiple infections as defined by hospital admission claims which are notoriously inaccurate, particularly for the two leading causes of infections (UTI and urosepsis). Since there is no deadline required for implementation, this should not be put into rule making prior to NQF endorsement.

**The Society for Healthcare Epidemiology of America**

SHEA continues to oppose the adoption of the measure, "MUC2021-124 Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization" for use in the SNF Value-Based Purchasing Program. While SHEA unequivocally supports efforts to improve the quality of care delivered in the long-term care setting through the SNF VBP, SHEA continues to have concerns that the HAI measure as proposed will create a strong disincentive to transfer residents to acute care, adding even more to concerns about penalties and fines than currently exist. As an alternative to the HAI measure as proposed, SHEA continues to recommend consideration of a requirement like that implemented in select states where at least one person trained in infection control be available at the facility, with their hours predicated on the number of beds.

- HAI measure identifies HAIs based on ICD-10 codes upon admission to the hospital. While it may seem that using ICD-10 codes in the long-term care (LTC) setting for quality measurement would be helpful in alleviating reporting burden, there have been many publications describing the inaccuracies of using administrative data to define HAIs. CMS should instead consider the revised McGeer criteria, which assess infections in LTC settings. CMS should also carefully consider using alternate thoughtfully developed definitions to assess infections in LTC settings that are grounded in evidence, agreed upon by experts, and already used in real-world settings.
- In addition to general concerns about the accuracy of using ICD-10 codes for surveillance, the HAI measure relies on an assumption that hospitals would correctly and accurately classify symptoms and diagnoses upon admission so that these data can be used to assess the quality of care delivered in the LTC setting. It also assumes patients being transferred from an acute care setting to a SNF are clinically stable at the time of discharge. Both assumptions do not bear out in practice.
- The proposed HAI score includes heterogeneous types of infections, many of which are non-

preventable. Using a composite score makes it difficult to target interventions toward prevention. For example, how will SNFs decide on a targeted intervention (e.g., hand hygiene, antibiotic stewardship, etc.) if the score is high without knowing which metrics are driving the overall score?
- Many of the infections listed in the ICD-10 code are not related to management of the patients in the post-acute setting.
- Patients may be admitted to a SNF with incomplete culture data resulting in a diagnosis that inappropriately attributes infection or colonization to the SNF. Common examples of such instances are outlined below:
- In the case of urinary tract infections (UTI), many patients are admitted with UTI due to abnormal urinalysis and are likely to have asymptomatic bacteriuria. For example, if a resident falls, is sent to the hospital and while being evaluated for injury, a urinalysis finds the resident has an Extended Spectrum Beta-Lactamase (ESBL) in the urine. The ESBL is present on admission to the hospital, but is it considered an HAI from the SNF because a hospital provider may insist on treating the positive urine before they will proceed with further treatment? Will the administrative data be able to identify this as asymptomatic bacteriuria?
- Many patients are originally diagnosed with "sepsis" but, upon further workup, have a non-infectious reason for their illness.
- The definition and timing for hospital-onset, SNF-onset and undetermined C. difficile infection has been the focus of much research. Even with this single pathogen that causes one clinical syndrome and which is readily detected by tests available to SNFs, there is a great deal of discussion about the attribution of the infection.
- It is also very difficult to determine which provider should be ascribed responsibility for an infection that occurs post discharge. For example: If a resident develops a wound at a hospital and comes to a SNF for care for that wound, which later becomes infected with a multi-drug resistant organism infection, should the infection be attributed to the hospital? Or the SNF? The hospital created the pre-existing condition and the SNF is the place where the wound was determined to be infected.
- The recommendation for including a four-day after SNF admission for determination of an HAI is not reflective of the clinical events involved with an HAI. The incubation period for some of the infections are longer than four days (e.g., Hepatitis B and C).

### Johnson & Johnson

Johnson & Johnson agrees with the Workgroup's recommendation for conditional support for rulemaking, pending NQF endorsement. Most healthcare associated infections (HAIs) are considered potentially preventable because they are outcomes of care related to processes or structures of care. Infection prevention and control programs with core components in education, monitoring, and feedback on infection rates from surveillance programs or feedback on infection control practices from audits have been found to be successful interventions for reducing HAIs. Measuring HAIs among SNF residents can therefore provide valuable information about SNFs' quality of care.

Johnson & Johnson supports measures that incentivize management and reduction of HAIs, which are important to manage, especially in high-risk settings such as Skilled Nursing Facilities. Preventing and reducing HAIs is crucial to delivering safe and high-quality care across the health care system and has been a priority objective at the federal, state, and local levels.

### American Hospital Association

The AHA disagrees with the MAP's recommendation of Conditional Support and instead recommends a position of Do Not Support. There is no doubt that preventing HAIs in SNFs is a top priority, and that this measure conceptually fits CMS' Meaningful Measure priority area of "Make Care Safer by Reducing Harm Caused in the Delivery of Care: Healthcare-associated Infections." However, in the interest of

achieving a streamlined and meaningful set of quality measures which will inform both care delivery and patient choice, we have several concerns regarding the specifications of this measure. In short, while we agree that measuring HAIs in SNFs is vital, the topic is so important and complex that CMS should develop a measure that will deliver timely, accurate and actionable information rather than this measure under consideration. As such, it is certainly not appropriate for use in the SNF VBP program.

In evaluating whether there is a performance gap regarding HAIs in SNFs, the Technical Expert Panel (TEP) Summary Report states "the literature is scarce on the epidemiology of HAIs in SNF…Most other estimates on infections for SNF residents come from studies with the broader population of nursing home residents. Even these estimates are uncertain, and many are outdated." Although we do not argue the gravity of HAIs in SNFs, the inability to define the magnitude of the issue makes it difficult to identify benchmarks and goals.

The most glaring issue with the measure is its data source. Claims-based measures for health outcomes like infections are not usable for improvement, nor are they reliable indicators of performance. No current Medicare HAI measure is informed by claims. In other quality reporting programs, HAIs are reported via the National Healthcare Safety Network (NHSN) using chart-abstracted surveillance data; these data are based on certain counts of bacteria or certain test results gathered using very detailed instructions about what cases to include or not in the denominator and clinical definitions that only an infection prevention expert can interpret. This scientific process ensures data integrity and provides analytic tools that enable each facility to assess progress and identify where additional efforts are needed. A claims-based measure would not provide this insight into clinical care for several reasons, including the multi-year lag between when claims are submitted and when data are used to inform measure performance.

CMS itself has found that administrative claims data are not reliable to inform HAI measure performance. For example, in a 2012 reliability analysis, CMS's contractor found that several claims-based hospital-acquired condition (HAI and patient safety indicator) measures had low and very low reliability; a 2012 Medicaid report on state reporting of the central line-associated blood stream infection (CLABSI) measure found that "administrative data (discharge or claims-based) substantially underestimate rates of CLABSI…effectively ruling out the use of administrative data at the current time as a legitimate approach to generating state-level, insurance-specific rates." In regards to ICD-9 (now ICD-10) coding that informs claims, the 2013 National Action Plan to Prevent Health Care-Associated Infections noted "coded diagnosis of UTI, CAUTI, and CDI is neither a sensitive nor a specific indicator of clinical diagnosis." Several other studies show that administrative data is not able to reliably predict outcomes. The literature review conducted by contractor RTI International for the TEP cited additional studies that concluded that administrative data (i.e., claims data) results in under-, over-, and misclassified reporting of health outcomes.

This measure's reliability also is questionable due to upstream data collection issues – namely, in detection of HAIs. As constructed, the measure would include only those SNF patients who go from a SNF to an acute care hospital, and for which the hospital submits a Medicare claim indicating BOTH that the HAI was the principal admitting diagnosis AND had the HAI at the time of admission (i.e., with a present on admission code). At a minimum, this construction is likely to omit some SNF patients who have an HAI simply because the HAI is not either recorded as the principal diagnosis, or present on admission. Nevertheless, the supporting documents for this measure conclude that existing HAI measures "all report on specific types on infections rather than on the overall HAI rate," and thus this measure, a composite of-sorts, would fill a gap. There is a reason that existing HAI measures are

specified as such: tests for various infections are different, with different levels of sensitivity and specificity. With such varying inputs, it is difficult to see how a composite measure would provide accurate (and thus actionable) information. In addition, hospital tests of HAIs vary as well; it is possible that certain hospitals will be better able to detect HAIs than others, and thus SNF performance might be a factor of hospital data collection rather than true quality of care.

Overall, the actionability of the measure – that is, whether providers will be able to use information gleaned from this measure to improve quality – is unclear. While there are common-sense practices that lower the likelihood of HAIs in SNFs, most specific clinical interventions are defined for the hospital setting rather than the SNF setting. Without clear clinical evidence of the relationship between the provider's actions in a SNF and the resident's health as a result of his/her stay, the measure may not be able to detect usable information.

In addition, the construction of this measure makes the assumption that the only HAIs that truly "matter" are those resulting in hospitalization. Yet, successful HAI reduction efforts depend on the rapid and timely identification of infections so that their underlying causes – infection control, environmental, physical plant, etc. – can be addressed before they result in morbidity or mortality. That is why existing HAI measures use detailed surveillance definitions we describe above, and are collected using actual medical record data. This approach ensures that providers know quickly which patients are infected, and can rapidly take infection control steps to protect other patients and staff from infection. Patients and providers cannot afford to wait two to three years to have incomplete claims-based data inform HAI reduction efforts. And for the reasons we describe below, this claims-based measure is likely to be a poor reflection of providers' actual performance.

Several factors at the patient and provider level influence outcomes, but they are not incorporated into the risk adjustment methodology for this measure. The supporting literature states "Research suggests that infection rates vary by provider characteristics" including staffing levels, staffing type (i.e., RN versus LPN), organizational structure (i.e., national chain versus independent facility), case mix, payer mix, and adoption of infection surveillance and prevention policies. Several other provider characteristics that may affect performance have not yet been investigated, including size, market (rural/urban or region) and whether the SNF is hospital-based. NHSN also collects information on patient days in admission, teaching status, and where microbial testing is done (in the facility versus a commercial reference lab).

Patient-level characteristics, which are outside of the provider's control, also influence infection rates. Literature shows that social risk factors, including income level and race/ethnicity are associated with varying infection rates due to "more disparities in access to care among patients in the community than in SNFs," suggesting that certain residents are less likely to receive preventive care in the community and are thus at increased risk of infection. A more precisely-constructed HAI measure may not need to account for social risk factors because the surveillance definitions are specific enough to ensure they are truly reflecting those infections acquired in the course of receiving health care. But this measure does not have such definitions, making it vital that the role of social risk factors in performance be assessed and accounted for if appropriate.

Because of the myriad factors affecting outcomes like HAIs, a composite measure such as this one may not provide information that providers can use to address specific risks to their patients. Even if the information gleaned from this measure were reliable, however, additional barriers remain to putting that data to use. While SNFs agree with the need to reduce HAIs, many operate under significant

financial strain, and may not have the same depth of resources to apply to quality improvement efforts. We encourage CMS to deploy quality improvement support to help accelerate progress on reducing HAIs in SNFs. This model has worked incredibly well for hospitals, as evidenced by the rapid progress of CMS's Hospital Innovation and Improvement Networks. It is conceivable that smaller SNFs with fewer resources could appear to perform worse than their competitors through no fault of their own (i.e., based on the influence of patient-level factors or differences in hospital surveillance). In the future, this measure might be incorporated into the SNF Value-based Purchasing program, in which the described scenario would result in direct financial harm to already disadvantaged facilities.

In the end, accountability measures like this one are useful only when they can accurately characterize performance. SNFs would welcome a well-designed measure that can help them understand where they are performing well, and where they can improve. However, for the reasons outlined above, we are not confident that this measure delivers on that critically important task. It is also challenging to conceptualize an evaluation of facility performance based on claims filed by a totally different facility; we understand and appreciate that CMS is seeking measures that do not pose undue burden on providers (as claims-based measures require no data submission on the part of providers), but for some topics the burden is worthwhile. Burden is outweighed by the benefits of truly meaningful measures that uncover discrepancies in performance and provide actionable data that will result in better patient outcomes. We suggest CMS scrap this measure and develop one that is timely and actionable.

MUC2021-137 Total nursing hours per resident day

## Section 1: Measure Information

*Measure Specifications and Endorsement Status*

**Program**
Skilled Nursing Facility Value-Based Purchasing Program

**Workgroup**
PAC/LTC

**Measure Description**
Total nursing hours (RN + LPN + nurse aide hours) per resident day. The source for total nursing hours is CMS's Payroll-based Journal (PBJ) system. The denominator for the measure is a count of daily resident census derived from Minimum Data Set (MDS) resident assessments. The measure is case-mix adjusted based on the distribution of MDS assessments by Resource Utilization Groups, version IV (RUG-IV groups).

**Numerator**
Total nursing hours (RN + LPN + nurse aide hours). The source for total nursing hours is CMS's Payroll-based Journal (PBJ) system. RN hours include RN director of nursing, registered nurses with administrative duties, and registered nurses. LPN hours include licensed practical/vocational nurses with administrative duties and licensed practical/ vocational nurses. Nurse aide hours include certified nurse aides, aides in training, and medication aides/technicians. The nurse staffing hours reported through PBJ are aggregated (summed) across all days in the quarter.

**Numerator Exceptions**
N/A

**Denominator**
The denominator of the measures is a count of daily resident census, derived from MDS resident assessments. The daily MDS census is aggregated (summed) across all days in the quarter.

**Denominator Exclusions**
A set of exclusion criteria are used to identify facilities with highly improbable staffing data and these facilities are excluded. The exclusion criteria are as follows:

- Total nurse staffing, aggregated over all days in the quarter that the facility reported both residents and staff is excessively low (<1.5 hours per resident day)
- Total nurse staffing, aggregated over all days in the quarter that the facility reported both residents and staff is excessively high (>12 hours per resident day).
- Nurse aide staffing, aggregated over all days in the quarter that the facility reported both

residents and staff is excessively high (>5.25 hours per resident day)

In addition, CMS conducts audits of nursing homes to verify the data submitted (both PBJ and census) Facilities that fail to respond to these audits and those for which the audit identifies significant discrepancies between the hours reported and the hours verified receive a one-star rating for overall staffing and RN staffing for three months from the time at which the deadline to respond to audit requests passes or discrepancies are identified. These facilities are also excluded from this measure.

In addition, only days that have at least one resident in the daily census are included in the calculation of total nurse staffing hours per resident day.

**Denominator Exceptions**

N/A

**State of development**

Fully Developed

**State of Development Details**

A measure of total nurse staffing per resident day has been reported on Nursing Home Compare for many years.

In 2003, the National Quality Forum Nursing Home Steering Committee recommended that a nurse staffing quality measure be included in the set of nursing home quality measures that are publicly reported by CMS. In 2004, the Institute of Medicine (IOM) report, entitled “Keeping Patients Safe: Transforming the Work Environment of Nurses” cited evidence for a relationship between nurse staffing and quality of care. The report also included recommendations for the collection and reporting of staffing data. In November 2007, individuals representing long-term care research, the National Association of State Long-Term Care Ombudsman Programs, and a long-term care employees union, testified before the Senate Select Committee on Aging, recommending that CMS use staffing data collected from nursing homes as the source of the nurse staffing measure.

Development of the PBJ system built on several earlier studies that included extensive testing of payroll-based staffing measures.

CMS’s Report to Congress on the Appropriateness of Minimum Staffing Ratios in Nursing Homes (1999) was the first study that tested the use of payroll-based staffing measures. As part of this study, payroll data were collected for a sample of 107 facilities in Ohio, using data from 1997. While this data collection effort was very different from PBJ, the study showed that payroll data could be used as the source for staffing measures and that there were differences in staffing levels from payroll records and other sources.

In 2003, CMS funded the initial phase of the Development of Staffing Quality Measures – Phase I (SQM) project, contracting with the Colorado Foundation for Medical Care (CFMC). The project was designed to investigate staffing measures for the purposes of public reporting that may be related to quality of care, including staffing levels (staff hours per resident day), staff turnover, staff tenure, and staff mix. Following the recommendations of the project’s Technical Expert Panel (TEP) during the initial phase of the project to develop staffing measures based on payroll information to achieve the highest level of accuracy, the project team collected payroll data from eight national nursing home corporations. This

activity led to the construction of a database with payroll records from 1,453 nursing facilities representing 48 states. The database consisted of more than 11.6 million individual payroll records and 172,563 individual personnel records. The study demonstrated that payroll data can be used to generate uniformly defined quality measures that are not available from other data sources. It found that reporting staffing data through payroll records offers the least burdensome and most accurate method of collecting staffing data. The final report for the project is available here: https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/nursinghomequalityinits/downloads/nhqisqmfinalreport.pdf.

CMS's Nursing Home Value Based Purchasing (NHVBP) was a three-year demonstration that ran from 2009-2012. Payroll data submitted quarterly by demonstration participants was used as the source data for the staffing performance measures used in the demonstration. The demonstration found that collecting payroll data directly from homes provided more accurate, reliable, and timely data than staffing measures from other potential data sources.

Nursing homes began reporting staffing data through the PBJ System in October 2016. In the early stages of the PBJ program, some facilities experienced challenges with submitting complete and accurate data. For example, some facilities did not report staffing data for every day in a quarter, resulting in staffing level calculations that were too low. Ongoing analyses of PBJ submissions were used to determine when the data were complete enough to be used as the source data for publicly reported measures. Over time, the number of nursing homes submitting staffing data increased. By the time that CMS started using PBJ as the source for staffing data for public reporting, the percentage of nursing homes submitting data had increased from 95.2% for 2017Q1 to 97.4% for 2020Q4. Also, the quality of the data increased. In 2017Q1, 11 percent of nursing homes would have had their data excluded from public reporting for one of the denominator exclusions described above. By 2020Q4, this decreased to 4.3 percent.

**What is the target population of the measure?**
All Medicare and/or Medicaid certified nursing homes in the United States

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

**Measure Type**
Structure

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

**If Other, Please Specify**
N/A

**What data sources are used for the measure?**
Standardized Patient Assessments; Other: PBJ, Minimum Data Set

**If applicable, specify the data source**
N/A

Total nursing hours per resident day

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

**At what level of analysis was the measure tested?**
Facility

**In which setting was this measure tested?**
Nursing home; Skilled nursing facility

**What one healthcare domain applies to this measure?**
Person-Centered Care

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

**CMIT ID**
N/A

**Alternate Measure ID**
N/A

**What is the endorsement status of the measure?**
Never Submitted

**NQF ID Number**
N/A

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

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

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

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

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

**Submitter Comments**
For the Five-Star quality rating system, CMS adjusts the measure for case-mix, using the Resource Utilization Group (RUG-IV) case-mix system. The CMS Staff Time Resource Intensity Verification (STRIVE) Study measured the average number of RN, LPN, and nurse aide minutes associated with each RUG-IV group (using the 66-group version of RUG-IV). We refer to these as “case-mix” hours”.

CMS calculates case-mix adjusted hours per resident day for each facility for each staff type using this formula:

Total nursing hours per resident day

Hours Adjusted = (Hours Reported/Hours Case-Mix) * Hours National Average

The reported hours are those reported by the facility through PBJ as described above. National average hours for a given staff type represent the national mean of case-mix hours across all facilities active on the last day of the quarter that submitted valid nurse staffing data for the quarter.

The case-mix values for each nursing home are based on the daily distribution of residents by RUG-IV group in the quarter covered by the PBJ reported staffing and estimates of daily RN, LPN, and nurse aide hours from the CMS STRIVE Study. Based on this distribution, we calculate case-mix nurse staffing hours for nursing homes for the quarter.

## *Digital Measure Information*

**Is this measure an electronic clinical quality measure (eCQM)?**
No

**If eCQM, enter Measure Authoring Tool (MAT) number**
N/A

**If eCQM, does the measure have a Health Quality Measures Format (HQMF) specification in alignment with the latest HQMF and eCQM standards, and does the measure align with Clinical Quality Language (CQL) and Quality Data Model (QDM)?**
N/A

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

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

## *Measure Use in CMS Programs*

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

**Previous Measure Information**
N/A

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

**Range of years this measure has been used by CMS Programs**
Total nursing hours per resident day has been publicly reported on Nursing Home Compare for many years and has been used in the Nursing Home 5-Star Quality Rating System since its inception in 2008. As noted above, the data source for the measure changed in 2018, when CMS started collecting payroll-based staffing measures through the PBJ system.

**What other federal programs are currently using this measure?**
Nursing Home Care Compare and Nursing Home Five-Star Quality Rating System

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

**Which measure(s) already in a program is your measure similar to and/or competing with?**
N/A

**How will this measure be distinguished from other similar and/or competing measures?**
N/A

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

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

## *Measure Evidence*

**Briefly describe the peer-reviewed evidence justifying this measure**
Staffing is a vital component of quality care for nursing home residents. Numerous studies have examined the relationship between nursing home staffing levels and quality of care. The findings of these studies have been mixed, although most studies have found a positive relationship [1-5]. Previous studies have varied considerably with respect to how they measured both staffing and quality. While not all studies have found a consistent relationship, associations have been found between higher staffing levels in nursing homes and fewer hospitalizations [6,7], fewer pressure ulcers [8, 9], less weight loss [6, 9], fractures [10], decreased resistance to care [6] , improved functional status [6, 11], improved pain management [12] and fewer survev deficiencies [13,14]. The strongest relationships have been identified for RN staffing [1, 2]. Major methodological and theoretical limitations in some studies, including poor quality staffing data, small sample size, and the quality measures used, limit the interpretation of results [2-3].

One of the most comprehensive studies to date [6] used Medicaid Cost Report data from 10 states with over 5,000 facilities to examine the relationship between staffing and hospitalizations of nursing home residents. The study found evidence of a relationship between higher staffing and better outcomes for total nurse staffing levels up to 4.08 hours per resident day and RN staffing levels up to 0.75 RN hours per resident day. Minimum staffing levels at any level up to these thresholds were associated with incremental quality improvements, and no significant quality improvements were observed for staffing levels above these thresholds.

**References:**

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[2] Dellefield ME, Castle NG, McGilton KS, Spilsbury K. The relationship between registered nurses and nursing home quality: an integrative review (2008–2014). Nurs Econ. 2015;33(2):95–108, 116.

[3] Bostick JE, Rantz MJ, Flesner MK, Riggs CJ. Systematic review of studies of staffing and quality in nursing homes. J Am Med Dir Assoc. 2006;7:366–376.

[4] Castle N. Nursing home caregiver staffing levels and quality of care: a literature review. J Appl Gerontol. 2008;27:375–405.

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[7] Carter, M. W., and F. W. Porell. ‘‘Variations in Hospitalization Rates among Nursing Home Residents: The Role of Facility and Market Attributes.’’ Gerontologist 2003 43 (2): 175–91.

[8] Alexander, G.L. An analysis of nursing home quality measures and staffing. Qual Manag Health Care. 2008;17:242–251

[9] Castle NG, Anderson RA. Caregiver staffing in nursing homes and their influence on quality of care: Using dynamic panel estimation methods. Med Care 2011;49:545-552.

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Nurs Care Qual 2007;22(1):59–65.

[11] Spector W, Shaffer T, Potter DE, et al. Risk factors associated with the occurrence of fractures in U.S. nursing homes: Resident and facility characteristics and prescription medications. J Am Geriatr Soc 2007 55:327-333.

[12] Horn SD, Buerhaus P, Bergstrom N, et al. RN staffing time and outcomes of long-stay nursing home residents: Pressure ulcers and other adverse outcomes are less likely as RNs spend more time on direct patient care. Am J Nurs 2005 6:50-53.

[13] Harrington, C., D. Zimmerman, S. L. Karon, J. Robinson, and P. Beutel. ‘‘Nursing Home Staffing and Its Relationship to Deficiencies.’’ Journal of Gerontology Series B: Psychological Science and Social Science 55 (5). 2000: S278–87.

[14] Lin, Haizhen, ‘Revisiting the relationship between nurse staffing and quality of care in nursing

homes: An instrumental variables approach’, Journal of Health Economics 2014 37: 13 – 24

**Evidence that the measure can be operationalized**

The measure is already operational. Since April 2018, CMS has been using PBJ and the MDS as the source data for this measure for public reporting on Nursing Home Compare (now Nursing Home Care

Compare) and for use in the Five-Star Quality Rating System.

**How is the measure expected to be reported to the program?**
Other: Through the PBJ system

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

**Evidence of Performance Gap**
For 2020Q4, average total nurse staffing was 4.09 hours per resident day for the case-mix adjusted total nurse staffing measure. There was considerable variability across nursing homes:

- 5th percentile: 2.81
- 10th percentile: 3.04
- 25h percentile: 3.43
- 50th percentile: 3:94
- 75th percentile: 4.57
- 90th percentile: 5.32
- 95th percentile: 5.93

Given the strong evidence of a relationship between higher nursing home staffing levels and better quality, this distribution shows that the nurse staffing levels at many nursing homes are below the level associated with high quality.

**Unintended Consequences**
We do not believe that there are unintended consequences given that the data for the measure are already being collected and the measure has been publicly reported on Nursing Home Care Compare and used in the Nursing Home Five-Star Quality Rating System for many years.

**Outline the clinical guidelines supporting this measure**
N/A—This is not a clinical measure.

**Were the guidelines graded?**
N/A

**If yes, who graded the guidelines?**
N/A

**If yes, what was the grade?**
N/A

**Estimated Impact of the Measure: Estimate of Annual Denominator Size**
In April 2021, staffing data were reported for 14,645 nursing homes on Nursing Home Care Compare.

**Estimate of Annual Improvement in Measure Score**
Staffing levels have increased since April 2018, when CMS first started reporting PBJ-based staffing measures on Nursing Home Compare and using them in the Five-Star Quality Rating System. Average nursing staffing hours per resident day increased from 3.85 in calendar 2017Q4 (publicly reported in April 2018) to 4.08 for 2020Q4 (publicly reported in April 2021).

Total nursing hours per resident day

**Type of Evidence to Support the Measure**
Empirical data

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

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

**Estimated Cost Avoided by the Measure: Estimate of Average Cost Savings Per Event**
Not applicable

**Cost Avoided Annually by Medicare/Provider**
Not applicable

**Source of Estimate**
Not applicable

**Year of Cost Literature Cited**
Not applicable

*Patient and Provider Perspective*

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

**If yes, choose all methods of obtaining patient/caregiver information**
Other: Stakeholder meetings with public consumer/patient advocates

**How many times and at what phase(s) of measure development was the patient/caregiver engaged?**
Engagement occurred at all phases of measure development.

The first engagement occurred with the CMS Development of Staffing Quality Measures, which had a stakeholder meeting in 2004 that was focused on development of payroll-based staffing measures. The most recent meeting was in June 2019, although it focused on other staffing measures such as turnover and non-nurse staffing.

We did not track the exact number of patients or caregivers that were consulted, but this measure has long had broad support. In addition, the use of PBJ as the data source for the measure went through the Rulemaking process. As discussed in the FY 2016 SNF PPS proposed rule, CMS adopted a multipronged strategy to solicit input from all interested parties through the rulemaking process and ongoing consultation with stakeholders regarding reporting specifications. The PBJ specifications in the FY 2016 SNF PPS final rule reflect the input that CMS received.

CMS collected input through regular stakeholder calls. The stakeholders represented a wide range of facilities throughout the country, including large and small, rural and urban, independently owned facilities and national chains. CMS consulted with facilities with varying types of payroll and time keeping systems. CMS published a Draft Policy Manual (‘‘1.0’’) for the PBJ system that offered more

details of planned technical specifications and solicited comments on the draft policy manual that were considered as they developed and refined the specifications that were i implemented in the final rule. In addition to input obtained through stakeholder meetings, CMS solicited input through a dedicated email address (NHStaffing@cms.hhs.gov).

In February 2017, CMS held a stakeholder meeting that included an overview of the PBJ system along with preliminary analytic results. Stakeholder input emphasized the importance of adjusting for resident acuity in measures used in the Nursing Home Five-Star Quality Rating System and about lessons learned from payroll vendors on improving data quality. There was also concern about how agency staff were captured in PBJ staffing measures. Stakeholders also suggested an override process for nursing homes that have their data suppressed if they can show that the submitted data are correct. They also discussed options for what staffing rating should be given to nursing homes that do not submit PBJ data. Preliminary analytic results showed that PBJ staffing levels were slightly lower, on average, than self-reported measures from CASPER.

In January 2018 CMS held stakeholder meetings with provider and consumer advocates that included discussion of the specifications for calculating total nurse staffing hours per resident day. Some stakeholders felt that nurses with administrative duties and nurse aides in training should not be included; others felt that these staff should be included since their role is important and they do provide some direct care. There was also disagreement about whether the staffing measures should be adjusted for differences in resident acuity. Some advocates opposed any acuity adjustment, while others supported CMS plans to update to use RUG-IV for risk adjustment. There was also discussion of what changes to the methodology for determining staffing ratings might be appropriate with the switch to PBJ-based staffing measures. There was support for giving a one-star rating to nursing homes with more than a small number of days with no RN staffing.

Another set of stakeholder meetings took place in June 2018. These occurred after CMS started using PBJ as the source for the staffing measures that are publicly reported and used in the Five-Star Quality Rating System in April 2018. The meeting included an update on the trends around completeness and quality of the PBJ data and a discussion of the PBJ audit process. The most common source of error was reporting meal breaks, If a meal break is available, it should be removed every day for employees, regardless of whether the break is taken. We also discussed with stakeholders the PBJ public use file that CMS started creating in April 2018.

**Total Number of Patients and/or Caregivers Consulted**

50

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

N/A

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

50

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

No

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

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

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

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

**If yes, choose all methods that obtained clinician and/or provider input**
Standard TEP; Other: Stakeholder meetings

**Total Number of Clinicians/Providers Consulted**
50

**Total number of clinicians/providers who agreed that the measure was actionable to improve quality of care**
50

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

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

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

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

**Does the measure require manual abstraction?**
No

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

**How many data elements will be collected for the measure?**
7

*Measure Testing Details*

**Reliability Testing Interpretation of Results**
The results demonstrate the reliability of nurse staffing measures created from PBJ data.

**Type of Reliability Testing**
Data Element Reliability

Total nursing hours per resident day

**Reliability Testing: Type of Testing Analysis**
Other: Audit findings

**Reliability Testing Sample Size**
Varies

**Reliability Testing Statistical Result**
An OIG Report found that "CMS uses several tools to check the accuracy and completeness of nurse staffing data.

These actions include checks for highly improbable nurse staffing and targeted audits of the nurse staffing data that nursing homes submit." (https://oig.hhs.gov/oei/reports/OEI-04-18-00451.pdf)

CMS has contracted auditors to assess and improve the accuracy of nurse staffing data, and these auditors performed nurse staffing audits at an average of 390 nursing homes each quarter from Q2 2018 through Q1 2019. Nursing homes that do not pass the audit are downgraded to a 1-star Staffing Rating. Nursing homes can fail a staffing audit if (a) CMS found a significant discrepancy between reported and verified hours or (b) nursing homes did not respond to an audit.

While not traditional reliability testing, the PBJ audit contractor uses a set of triggers to identify nursing homes with potentially aberrant PBJ data. These include employees with more than 500 hours worked reported in a single month, more than six total nursing hours per resident day, nursing homes with a change of more than 15% across quarters in nurse staffing level, and nursing homes with a decrease of 12% or more in their daily census. Even with a focus on nursing homes that are most likely to have data reliability issues, the audit contractor (Myers and Stauffer) has found that most of the reported data are accurate. For example, for audits conducted of staffing data submitted in 2020, of the 32 facilities with reported nurse staffing greater than 6 hours per resident day, 17 had no significant variance, 14 had a slight variance, and only one had their staffing rating downgraded due to a significant variance. Only one nursing home had reporting of their staffing data suppressed due to an increase in reported staffing levels. In total, for the most recent quarter, seven nursing homes had their staffing rating downgraded due to PBJ reporting issues (six based on issues identified by the audit contractor and one self-report). These findings support the reliability of the nurse staffing measure.

CMS uses information from audits to issue guidance to nursing homes, for example, highlighting common types of errors found in PBJ submissions and hopefully improving the quality of submitted data.

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

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

**Type of Validity Testing**
Measure Score Validity

**Validity Testing: Type of Validity Testing Analysis**
Correlation;Face Validity;Internal Consistency;Predictive Validity

Total nursing hours per resident day

### Validity Testing Sample Size
Varies across different analyses

### Validity Testing Statistical Result
The Phase II CMS report "Appropriateness of Minimum Nurse Staffing Ratios in Nursing Homes," completed in 2001, showed the relationship between quality and nurse staffing levels using several methods, establishing the face validity of the total nurse staffing per resident day measure. The study included an analysis of data from 10 states with over 5,000 facilities that found evidence of a relationship between staffing ratios and the quality of nursing home care.

The findings were also supported by case studies of individual facilities, units, and residents.

Analyses of PBJ-based staffing measures shows a relationship between higher nursing staffing levels and higher ratings for other dimensions of quality such as health inspection survey results and quality measures. In April 2021, we observed the following relationship between five-star ratings and average nurse staffing hours:

**Health inspection rating:**

- One-star health inspection rating: 4.00 hours
- Two-star health inspection rating: 4.17 hours
- Three-star health inspection rating: 4.27 hours
- Four-star health inspection rating: 4.38 hours
- Five-star QM rating: 4.82 hours Health inspection rating:

**QM Rating:**

- One-star quality measure rating: 4.12 hours
- Two-star quality measure rating: 4.23 hours
- Three-star quality measure rating: 4.09 hours
- Four-star quality measure rating: 4.18 hours
- Five-star quality measure rating: 4.38 hours

In addition, a soon-to-be published article in the Journal of the American Gerontological Society (The Association of Nursing Home Quality Ratings and Spread of COVID-19) found that higher staffing levels were associated with fewer confirmed COVID-19 cases and deaths.

### Validity Testing Interpretation of Results
These results demonstrate both the face and the external validity of the nurse staffing hours per resident day measure.

We note that payroll data are considered to be the gold standard for nurse staffing measures and a significant improvement over the self-reported data that had previously been used. Recognizing the benefits of payroll-based staffing measures, Section 6106 of the Affordable Care Act (ACA) requires facilities to electronically submit direct care staffing information based on payroll and other auditable data.

### Measure performance – Type of Score
Mean

Total nursing hours per resident day

**Measure Performance Score Interpretation**
Higher score is better

**Provide mean performance rate and standard deviation for each submission method a measure has or is anticipated to have**
For 2020Q3 (the most recent quarter for which data are available), the mean is 4.083 hours per resident day, and the standard deviation is 1.047.

**Benchmark, if applicable**
N/A

*Measure Contact Information*

**Measure Steward**
Centers for Medicare & Medicaid Services

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## Section 2: Preliminary Analysis – MUC2021-137 Total Nursing Hours Per Resident Day

**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 measures addressing staffing hours in the Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program. This measure is currently utilized in two publicly reported CMS programs, the Nursing Home Care Compare and the Nursing Home Five-Star Quality Rating System. Per the Consolidated Appropriations Act of 2021, up to nine additional measures may be added to the SNF VBP Program including those measures related to patient safety and patient experience. The developer cites evidence regarding the relationship between higher staffing levels in nursing homes and improved care for patients, the strongest relationship with registered nursing (RN) staffing. This measure aligns with CMS' current needs and priorities focus for this program, including addressing the Consolidated Appropriations Act of 2021 and optimizing measures already used in publicly reported programs.

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

**Yes/No:** Yes

**Justification and Notes:** Nursing staff including Registered Nurse (RN), Licensed Practical Nurse (LPN), and nurse aides, account for the majority of care delivery within skilled nursing facilities (SNFs) from care plan implementation to activities of daily living. The developer cites evidence regarding the relationship between higher staffing levels in nursing homes and improved care for patients, the strongest relationship with RN staffing. Those total nurse staffing levels included a threshold of 4.08 hours per resident day and RN staffing levels of 0.75 RN hours per resident day. Minimum staffing up to threshold levels indicated incremental quality improvements with no significant change for those above thresholds. The developer also cites an analysis of CMS' Payroll-based Journal (PBJ) system staffing measures that show a positive relationship between higher nursing staffing levels and higher ratings for other quality measures, including those developed from the Minimum Data Set (MDS) that address function and health status. The developer cites the April 2021 result of total nursing hours including RN, LPN, and nurse aide, concluding the highest reported hours of 4.38 were observed with the nursing home five-star quality measure rating. The five-star quality measure rating, the highest rating, is comprised of physical and clinical measures of nursing home patients. Those SNFs with a five-star rating are considered to have an above average quality than those with lower ratings.

### Does the measure address a quality challenge?

**Yes/No:** Yes

**Justification and Notes:** The COVID-19 Public Health Emergency has brought nursing home staffing to the forefront of an already frequently discussed topic. A recent report from the Office of Inspector General on CMS' use of data on nursing home staffing generated recommendations includes taking additional steps to strengthen the oversight of nursing home staff (U.S. Department of Health and Human Services, 2021). The developer reported for the 2020 Q4, average total nurse staffing was 4.09 hours per resident day for the case-mix adjusted total. There was considerable variability across nursing homes from the fifth percentile with 2.81 hours to the 95$^{th}$ percentile with 5.93 hours.

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

### Yes/No: Yes

**Justification and Notes:** There are no measures addressing staffing hours in the SNF VBP Program. This measure is currently utilized in two publicly reported CMS programs, the Nursing Home Care Compare and the Nursing Home Five-Star Quality Rating System. The importance of nursing home improvement has come to the forefront with a recently introduced bill in the Senate, The Nursing Home Improvement and Accountability Act of 2021 (Congress, 2021); improvements to staffing and oversight are addressed within this bill.

### Can the measure be feasibly reported?

**Yes/No:** Yes

**Justification and Notes:** The developer indicates all data elements are in defined fields in a combination of electronic sources. The numerator, total nursing hours, will be derived from CMS' PBJ system. The denominator, a count of daily resident census, will be derived from the minimum data set (MDS) resident assessments.

Total nursing hours per resident day

### 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 not currently NQF endorsed. This measure is specified and originally tested at the facility-level of analysis with skilled nursing facilities as the care setting. The target population is all Medicare and/or Medicaid certified nursing homes in the United States. Staffing levels have increased since April 2018, when CMS started reporting PBJ-based staffing measures on Nursing Home Compare and utilizing them in the Five-Star Quality Rating System. Average nursing staffing hours per resident day increased from 3.85 in 2017 Q4 to 4.08 for 2020 Q4.

### 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 is currently utilized in two publicly reported CMS programs. The developer indicates there will be no unintended consequences given that the data are already being collected and publicly reported on these two CMS programs for many years. Since April 2018, CMS has been using PBJ and the MDS as the source data for this measure for public reporting on Nursing Home Compare (now Nursing Home Care Compare) and for use in the Five-Star Quality Rating System.

### PAC/LTC Core Concept?

**Yes/No:** No

**Justification:** This measure does not meet one of the 13 PAC/LTC core concepts. Per the final report, staffing measures were not mapped to a core set concept.

### Impact Act Domain

**Yes/No:** No

**Justification:** This measure does not meet one of the 8 Impact Act domains. Staffing hours are not one of the addressed domains.

### Hospice High Priority Areas

**Yes/No:** N/A

**Justification:** N/A

### MAP Rural Health Advisory Group Input:

**Relative priority/utility:**

- The Advisory Group generally agreed with the importance of this measure and relevance to rural providers and care settings
- An Advisory Group member noted that in rural settings that non-nursing personnel are important in these rural care settings.
- The Advisory Group noted that this measure should be considered in the context of additional measures to get a holistic view of provider quality.

**Data collection issues:**

- None

Total nursing hours per resident day

**Calculation issues:**

- The Advisory Group noted concerns that nursing administrative hours is also included in the measure, not direct care hours.

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher is more relevant to rural.**
Average: 3.0
1 – 0 votes
2 – 5 votes
3 – 5 votes
4 – 5 votes
5 – 0 votes

### MAP Health Equity Advisory Group Input:

**Relative priority/utility:**

- The Advisory Group noted that this measure is an important quality measure for the care setting. They noted that LPNs are typically the staffing for this particular care setting and the Advisory Group was encouraged to see the multiple staff (RN + LPN + nurse aide hours) in the measure.
- The Advisory Group would like to see stratification of nursing hours spent by patient demographics
- Certain minority communities are more concentrated in for-profit SNFs, which have staffing concerns

**Data collection issues:**

- None

**Calculation issues:**

- The Advisory Group questioned in what ways this measure is risk adjusted for social factors, and the developer clarified that the measure is not adjusted for social needs

**Unintended consequences:**

- None

**Votes: Range is 1 – 5, where higher has greater potential for positive impact on health equity**
Average: 3.5
1 – 0 votes
2 – 4 votes
3 – 6 votes
4 – 10 votes
5 – 2 votes

*Recommendation*

**Preliminary Analysis Recommendation:**

Conditional Support for Rulemaking pending NQF endorsement.

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

This measure adds value to the SNF VBP program by adding a measure not currently addressed and aligns across other PAC/LTC programs by working towards CMS' Meaningful Measures 2.0 overarching goal of value-based care. Per the Consolidated Appropriations Act of 2021, expansion of the measure set will assess the quality of care that SNFs provide to patients. CMS reported average nursing staffing hours per resident day increased from 3.85 in 2017 Q4 to 4.08 for 2020 Q4. There is variation in the performance of this measure within SNFs and these facilities will have the ability to address processes to improve staffing.

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

Patients in skilled nursing homes are at greater risk for illness and staffing can aid or hinder patients' quality of care. The COVID-19 Public Health Emergency has brought nursing home staffing to the forefront of an already frequently discussed topic. A recent report from the Office of Inspector General on CMS' use of data on nursing home staffing generated recommendations includes taking additional steps to strengthen the oversight of nursing home staff (U.S. Department of Health and Human Services, 2021). The developer cites evidence regarding the relationship between higher staffing levels in nursing homes and improved care for patients, the strongest relationship with registered nursing (RN) staffing.

The condition for Support for Rulemaking is for the measure to be submitted to NQF for endorsement.

## Section 3: Public Comments

**American Occupational Therapy Association**

AOTA supports advancement of the CMS measure, Total Nursing Hours Per Resident Day, under the Skilled Nursing Facility (SNF) Value Based Purchasing (VBP) Program. AOTA asserts that it is appropriate to access data regarding total nursing hours from the CMS Payroll Based Journal System (PBJ). In the future, AOTA similarly recommends that NQF support the development of a new measure to monitor total therapy hours per resident as part of the SNF VBP. In addition to collecting valuable data regarding therapy hours per SNF resident, such a measure could support appropriate patient access to rehabilitation therapy following implementation of the Patient Driven Payment Model.

**AHCA**

This measure is not ready for use in the SNF VBP program for following reasons: (1) the SNF VBP program is designed to measure performance on outcomes not structural measures of quality. (2) the measure is not NQF endorsed and there is no statutory rush that makes adding measures to the NQF so urgent that it should by pass NQF endorsement (3) while there is an association between staffing levels and quality; at a certain level of staffing further increases are not associated with improved quality (as mentioned by the measure developers) but the SNF VBP program is based on ranking facilities on performance on each measure which creates an incentive to keep increasing staffing even if it has not

evidence to support higher staffing results in better quality. (4) this measure aggregates RN, LPN and CNA hrs into one measure which creates an incentive to use more LPN or CNA than RN which is contrary to the literature. The availability of staff to hire make this impossible to achieve and the cost will exceed the VBP payment.

**LeadingAge**

While we appreciate the low administrative burden of this measure, we think there are better staffing measures to be considered that directly reflect quality of care. There are so many types of staff that are critical to the care provided within nursing homes. The current environment has put enormous stress on the health care system and the staff who provide care. Given the current staffing crisis in health care and particularly in nursing homes, not to mention the ongoing pandemic, we cannot in good conscience support adding this measure at this time. If performance on a measure is to be tied to payment, it needs to be a measure that the nursing home can influence. At present, staffing levels are no longer a choice but a day-to-day battle to fill positions any way they can. Currently, temporary staffing agencies and in some states, national guard troops, are filling some of these gaps. It would be one thing to collect and track this data but implementing this as a measure tied to payment would only penalize most nursing homes at a time when their costs to recruit and retain staff has skyrocketed. This measure should not be included in the list of SNF VBP measures at this time. We think other measures might be more effective when a staffing measure is considered. Again, while COVID continues, along with the staffing crisis and vaccine mandates make the outcomes on this and other staffing measures an aberration. We do appreciate that this measure uses Payroll Based Journal and MDS data for its calculation, resulting in a lower administrative burden but can't support payment being tied to this measure when we believe the staffing crisis makes it nearly impossible for nursing homes to staff at their preferred levels. In addition, merely collecting data on the number of nursing staff hours doesn't really tell the whole story. A SNF could have adequate or above average level of staff but if they are all new on the job, they don't likely know the residents very well yet and may have additional training to complete. Finally, it would be challenging to implement this measure using a pre-COVID period as a baseline and comparing it to staffing levels during COVID-19. The two situations are incomparable.

**American Health Care Association**

While an important measure this is not appropriate for the proposed program for rule making. The SNF VBP program as inferred in the statute creating the program, is designed for adjusting Part A SNF payments on clinical outcome measures. The data on the relationship between staffing and quality is not linear but the SNF VBP program per statute compares performance on ranking of SNFs on the measure. The cost to achieve this measure will far exceed the payment adjustment which is based on withhold and inclusion of this measure in the VBP program will have the paradoxical effect of cutting resources needed to hire staff. This measure is already publicly reported and a key metric in the Five star rating program.

**American Hospital Association**

The AHA disagrees with the MAP's recommendation of Conditional Support for this measure and instead recommends a position of Do Not Support. While there is some evidence regarding the relationship between higher staffing RN staffing levels in nursing homes and improved care for patients, this measure oversimplifies this relationship and is unlikely to provide an accurate and meaningful indication of quality of care provided.

First, the measure does not solely evaluate the use of RNs, but rather the total nursing hours for RNs,

Total nursing hours per resident day

LPNs, nurse aides, medication aides/technicians and aides in training. While these clinicians are important parts of the caregiving team, there is less evidence available demonstrating a causal relationship between staffing hours for these professionals and patient outcomes.

In addition, the recent report from the Office of Inspector General cited by the measure developer comes to the conclusion that regulatory bodies should take "additional steps to strengthen the oversight of nursing home staff." Yet, this measure provides only a tally of hours—which would include not only nursing but administrative duties. Therefore, it is difficult to see how this measure provides meaningful insights on quality of care.

CMS first began monitoring payroll-based staffing state in early 2019 in response to claims that facilities often have fewer staff on weekends; this data was used to update lists of nursing homes with significant drops in staffing levels specific to RNs, which were given to state survey agencies. If CMS's goal is to enhance oversight of nursing homes, this targeted surveillance is a more appropriate way to do so than using a broad count of general staff hours in a value-based purchasing program.