Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalizations for the Skilled Nursing Facility Quality Reporting Program

Public Comment Summary Report

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1 OVERVIEW

1.1 Project Title

Development of the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program (SNF QRP).

1.2 Dates

- The Call for Public Comment ran from September 14 to October 14, 2020.
- The Public Comment Summary Report was finalized in December, 2020.

1.3 Project Overview

The Centers for Medicare & Medicaid Services (CMS) has contracted with Acumen, LLC to develop a claims-based quality measure of healthcare-associated infections (HAIs) for the SNF QRP. The contract name is Quality Reporting Program Support for the Long-Term Care Hospital, Inpatient Rehabilitation Facility, Skilled Nursing Facility/Nursing Facility QRPs and Nursing Home Compare (PAC QRP) Support (75FCMC18D0015). As part of its measure development process, CMS requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

1.4 Project Objectives

- Develop a healthcare-associated infections quality measure for the SNF QRP under the meaningful measure domain: Making Care Safer by Reducing Harm Caused in the Delivery of Care.
- Specify the target population, including the exclusion criteria.
- Identify risk adjustment variables and the approach for risk adjustment.
- Gather feedback on the importance, feasibility, usability, and potential impact of calculating an HAI measure.
- Identify additional guidance required for implementation in the SNF QRP.

1.5 Information about the Comments Received

We solicited public comments using the following methods:

- Posting a call for public comment on the CMS public comment website
- Email notification to relevant stakeholders and stakeholder organizations

We received 20 responses for the SNF HAI measure via email:

- Of the 20 received comments, one comment was received outside of the public comment period and another was out of scope. These two comments were not considered. The remaining comments were relevant and received during the public comment period. We respond to these 18 comments in this report.
- 18 organizations and 2 individuals submitted comments.
- Verbatim comments are at Appendix A, Section A.1.

2 STAKEHOLDER COMMENTS: GENERAL AND MEASURE-SPECIFIC

This section summarizes issues and questions raised by public commenters and provides clarification and responses to the public comments. Subsection 2.1 Measure Concept summarizes general feedback and comments related to measure concept in terms of its importance, actionability, feasibility, and usability. Subsection 2.2 Measure Specification outlines comments specific to the design and construction of the SNF HAI measure. Finally, Subsection 2.3 Measure Implementation details comments related to implementation issues, including unintended consequences and public reporting. The verbatim text of each submitted comment is presented in Appendix A.

2.1 Measure Concept

2.1.1 Importance

Comment Summary: CMS received several comments in support of the SNF HAI measure. These comments recognized the need for quality improvement in SNFs and the importance of HAI prevention. Several comments believed that HAI surveillance can improve management and prevention of HAIs.

Response: We appreciate your feedback and support. We agree that there is a critical need to reduce HAIs in SNFs and that monitoring SNF HAI rates provides valuable information on a SNF's quality of care. We believe this proposed quality measure will address the lack of HAI data in SNFs, increase transparency, and reduce rates of HAIs.

2.1.2 Feasibility

Comment Summary: Many supported the use of administrative data. These commenters supported the proposed data source because use of claims data will not create more data collection. One commenter was concerned that use of administrative data may be imprecise for HAI monitoring; however this commenter believed that the use of administrative data will ultimately lead to examination of current processes, collaboration, and improvement within and between facilities, leading to refinement toward a more precise measure.

Response: Thank you for your support. We agree that the measure is feasible due to the use of administrative data. Claims data are readily available and require no additional data submission beyond what is already collected on claims in the normal course of business.

Comment Summary: Several commenters were concerned about the measure's dependence on diagnoses from medical practitioners who are outside of the influence of the SNF. The measure outcome is calculated based on hospital information, not SNF information, so some commenters believed the measure is reflective of the coding practices of hospitals rather

than actual quality of care at SNFs. One commenter was concerned that differences in hospital surveillance practices and lack of standardization may result in arbitrary differences in HAI rates. Additionally, a few commenters raised the issue of poor transition of care between hospitals and SNFs. These comments claimed that many SNFs do not receive diagnostic records and antibiotic history from the prior inpatient (IP) provider, which affects the resident's care plan. One commenter believed that the measure will create provider burden since SNFs will need to spend more time on preadmission review due to potentially inaccurate and incomplete information from claims.

Response: Thank you for reviewing the measure and sharing your input. We recognize there are logistical difficulties in care transition, particularly with coordination of information between acute and PAC settings. There are ongoing efforts to improve the transfer of health information when patients transition across care settings, such as the Transfer of Health Information quality measures. We believe that the HAI measure along with the transfer of health information measures will encourage stronger organizational relationships and improve coordination and communication between entities.

It is ultimately the responsibility of the SNF to guarantee efficient transfer of healthcare information and we disagree that this measure creates additional burden during preadmission review. The information that SNFs already collect from hospitals includes sufficient information related to this measure. The SNF should already be reviewing information from the prior facility as part of routine clinical practice. This measure does not require any information that is beyond standard transfer of information and routine patient care planning. Moreover, reliance on IP data for SNF measures is not a new concept as several other existing quality measures rely on data from other settings such as Skilled Nursing Facility 30-Day Potentially Preventable Readmission after Hospital Discharge (SNFPPR), Skilled Nursing Facility 30-Day All-Cause Readmission (SNFRM) (NQF #2510), and Potentially Preventable 30-Day Post-Discharge Readmission Measure for Skilled Nursing Facility Quality Reporting. Regarding the appropriateness of using diagnosis codes for HAI identification and the accuracy of coding in IP claims, please see our response in subsection 2.2.3 HAI Identification.

2.1.3 Actionability, Usability, and Use

Comment Summary: One commenter expressed concern that the data delay for claims does not allow for timely improvement in HAI rate.

Response: Thank you for sharing your thoughtful concern. We acknowledge that there is a data delay issue with claims. In the future, we will consider performing a stability analysis on HAI rates to investigate the potential impact of this issue.

Comment Summary: Several commenters criticized the measure's calculation of overall HAI prevalence. These commenters believed that capturing overall HAI rate does not provide actionable data. One commenter stated that since different infection types have different tests, it is difficult and inaccurate to compile varying inputs into a composite form. Another commenter noted that the measure is made up over 300 diagnosis codes, which makes it difficult to isolate performance issues for quality improvement. A few commenters suggested that the measure would be more actionable if it was segmented by infection type, so the facilities can make specific improvements.

Response: We thank you for sharing your concerns. There is currently a dearth of information on HAIs in post-acute care, and the SNF HAI measure fills this gap by providing a summary picture of overall performance in infection control and management.

One of the benefits of composite indicators is their simplicity. A single score is easier to interpret, easier to use a benchmark for tracking performance, and easier to use for comparisons among peers. The measure is not intended to be a standalone measure, rather it can be used in conjunction with other surveillance activities to plan for quality improvement. While an overall HAI rate may not provide information for targeting HAI prevention efforts to specific infection types, we believe that aggregate HAI prevalence data still provides actionable feedback to SNFs. The prevention of HAIs is not specific to an individual type of infection. Rather, infection prevention and control efforts should address multiple infection types and SNFs should already be implementing infection control practices that includes various approaches such as vaccination, isolation, handwashing, antibiotic stewardship programs, surveillance, sanitation, and staff training. Therefore, a composite HAI rate is a reflection of the quality of care and measures the facility's adeptness in infection prevention and management.

Comment Summary: Many commenters expressed concerns about the measure's usability and actionability due to potential misattribution. These comments discussed the difficulty of HAI attribution due to risk factors that are outside of the SNF's control. Attribution in the SNF population is especially difficult because the resident and provider population in SNFs are very mobile. SNF residents leave the facility for other appointments and services and SNF staff work in multiple facilities with different quality standards, which exposes them to HAIs outside of the SNF. In particular, one commenter stated that it is difficult to determine if the HAI is attributable to the hospital or the SNF because often times the hospital creates the pre-existing condition and the SNF is the place where the infection is determined. This commenter asked: "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?"

Response: Thank you for the thoughtful comments and questions. HAIs are not considered as "never-events" and we acknowledge that residents may contract infections outside of the SNFs. However, it is the responsibility of the SNF to implement infection prevention protocols and to best manage infections when they do arise. To help determine attribution, the measure excludes certain community-acquired infections, implements an incubation window, and applies the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) Repeat Infection Timeframe (RIT) to exclude pre-existing infections that were acquired from the prior IP stay.[1]

Regarding the commenter's question about hospital vs. SNF attribution and the specific example on wound infection, our response is that the SNF is responsible for management and treatment of the wound. If the multi-drug resistant organism infection is within the HAI incubation window and the SNF resident did not have a pre-existing multi-drug resistant organism infection within the RIT as identified on the most proximal hospitalization claim prior to the SNF admission, then the HAI would be attributable to the SNF. See our response to comments in subsection 2.2.2 or refer to the Numerator Statement and Details section of the Draft Measure Specifications for details on the HAI incubation window and the Repeat Infection Timeframe. [2]

2.1.4 Measure Adoption

Comment Summary: Some commenters do not support adoption given the current measure design. These commenters raised several issues related to the actionability, usability, feasibility, unintended consequences, and specifications (e.g., use of diagnosis codes, included infection types, incubation window, risk adjustment, etc.). The specific criticism of these commenters are summarized throughout subsections 2.1, 2.2, and 2.3.

Response: Thank you for closely reviewing the SNF HAI measure and we acknowledge your concerns. Our responses to specific criticism of these commenters are addressed throughout subsections 2.1, 2.2, and 2.3 of this report. In summary, we believe that the measure meets the

[1]Centers for Disease Control and Prevention (CDC). (2020). *Identifying Healthcare-associated Infections (HAI) for NHSN Surveillance*. https://www.cdc.gov/nhsn/pdfs/pscmanual/2PSC_IdentifyingHAIs_NHSNcurrent.pdf

[2] Centers for Medicare & Medicaid Services (CMS). (2020). *Draft Measure Specifications: Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalizations for the Skilled Nursing Facility Quality Reporting Program*. https://www.cms.gov/files/document/development-skilled-nursing-facility-snf-healthcare-associated-infections-hais-requiring.pdf

standards for adoption. The measure does not impose additional provider burden, fills a gap in quality reporting programs, increases transparency, and provides useful information on HAIs in SNFs. To ensure that the proposed SNF HAI measure meets its stated goals, we developed the measure with stakeholder input and conducted measure reliability and validity testing. We will consider releasing full testing results in the future. 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. TEP members reviewed and agreed upon the study restrictions, conceptual and operational definition of the HAIs, and risk adjustment approach. For more information, refer to the Final TEP Summary Report for stakeholder input.[3]

2.2 Measure Specification

2.2.1 Study Population

Comment Summary: CMS received general support for study restrictions from many commenters.

Response: We thank commenters for their input regarding the study population and inclusion/exclusion criteria.

Comment Summary: CMS also received a couple of concerns about the proposed study population. One commenter was concerned about the long-term viability of the measure since it only includes Medicare Fee-for-Service (FFS) beneficiaries in the target population. This commenter observed that SNFs have a low number of Medicare FFS admissions and a growing Medicare Advantage population. Another commenter suggested increasing the age limit to 35 and excluding high risk residents (e.g., residents with multiple hospitalizations).

Response: We appreciate your feedback. The SNF HAI measure excludes residents enrolled in Medicare Advantage because this population may have incomplete claim information and the measure relies on inpatient claims. We will consider monitoring changes to the SNF enrollment by payer source and will re-specify the Medicare population as needed. In terms of age restrictions, the measure excludes residents under 18 years old because pediatric residents

[3] Levitt, A. T., Freeman, C., Schwartz, C. R., McMullen, T., Felder, S., Harper, R., Van, C. D., Li, Q., Chong, N., Hughes, K., Daras, L. C., Ingber, M., Smith, L., & Erim, D. (2019). *Final Technical Expert Panel Summary Report: Development of a Healthcare-Associated Infections Quality Measure for the Skilled Nursing Facility Quality Reporting Program*. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf

may have different patterns of care than adults. However, there is no clear clinical justification for limiting the age to 35 years. We also note that the population of Medicare SNF residents between 18-35 years old is very small. Finally, in response to the comment on high risk residents, the SNF HAI measure accounts for high risk residents such as those with multiple hospitalizations through risk adjustment. Please refer to our response to risk adjustment comments in subsection 2.2.4 and refer to the Statistical Risk Model and Variables section in the Draft Measure Specifications.[4]

Comment Summary: One commenter believed that the measure name is misleading and suggested renaming the measure to emphasize the FFS study population: "Skilled Nursing Facility (SNF) Healthcare-Associated Infections Associated with Fee-for-Service Stays Requiring Hospitalization."

Response: We appreciate your feedback. We believe that the measure as currently specified represents performance for all residents in a SNF, and do not agree in adding the data source to the measure name.

2.2.2 HAI Definition

Comment Summary: CMS received general support for the HAI definition. Such comments agreed with the restriction to HAIs that require IP hospitalization and exclusion of emergency room visits and observation stays. Multiple commenters supported the included/excluded infection types such as the inclusion of infections related to invasive but not implanted medical devices.

Response: We thank you for your support for the proposed HAI definition and appreciate your engagement in measure development.

Comment Summary: A few commenters disagreed with infections included in the HAI diagnosis list. These commenters claimed that the proposed HAI definition includes types of infections that are not preventable or are unrelated to management of patients in the post-acute setting. Commenters cited examples of unrelated and unpreventable infections, such as infection due to devices or stumps such as infection and inflammatory reaction due to implanted urinary neurostimulation device; infection and inflammatory reaction due to indwelling ureteral stent, infection of amputation stump; 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; neurologic infections meningococcal meningitis or other bacterial meningitis; bronchiectasis with acute lower

[4] Refer to Footnote 2

respiratory infection; candidal sepsis; and cellulitis. One commenter recommended reducing the scope of the measure to a limited list of infections.

Response: Thank you for feedback on the infection types included in the HAI measure. First, we would like to note that the inclusion and exclusion criteria for infection types was developed in collaboration with subject matter experts during the TEP meeting. This list was reviewed by TEP members and it was agreed upon that the list of HAI conditions reflect infections that are likely to be acquired during SNF care. See section 3.3.1 in the TEP Summary Report for details.[5] Second, we maintain that these conditions are preventable or can be managed during SNF care and thereby prevent hospitalization. While some conditions in the HAI diagnosis code list are a result of surgery in the IP setting, SNFs are responsible for surgical aftercare. Third, there are many precautions to prevent misattribution and exclude conditions unrelated to the SNF care, such as the RIT and HAI incubation window. If the HAI was caused by the hospital rather than the SNF, then the HAI would present during the IP stay or shortly afterward, such as within the first few days of the SNF stay. Accordingly, the HAI incubation window for SNF HAI measure begins on day four of the SNF stay to ensure that the measure does not count HAIs attributable to the IP stay. The application of the RIT excludes HAIs that were present during the prior hospitalization to prevent SNFs from being held responsible for ongoing or reoccurring infections.

Comment Summary: A few commenters disagreed with the inclusion of community acquired infections in the HAI diagnosis list since community acquired infections are outside of SNF control. These commenters noted that SNF residents may leave the facility for many reasons and acquire an infection while outside; therefore, such infection types should not be attributed to the SNF. Commenters cited examples of community acquired infections, such as salmonella, shigella, viral encephalitis, scabies, upper and lower respiratory infections (e.g., pneumonia, flu, strep throat, pharyngitis, tracheitis, and whooping cough), GI infections, and conjunctivitis.

Response: Thank you for sharing your concerns. First, we maintain that the example infections cited by commenters can be acquired from SNFs and are reflective of quality of care in the SNFs. For example, salmonella and scabies can be contracted due to poor sanitary conditions in the SNFs. Second, we would like to point out that the HAI measure excludes some infections that are likely to be community acquired. However, this exclusion is specific to community acquired infections that are unlikely to occur in a SNF (such as insect-related diseases like echinococcus granulosus) rather than viral infections such as flu, which could be transmitted in the normal process of care. While conditions such as shigella can be caused by

[5] Refer to Footnote 3

larger systemic forces (infection in the food supply chain) and can be contracted from outside of the SNF, the SNF should take precautions to prevent the infection, or if transmission does occur, manage the severity of the infection so that it does not require hospitalization.

Comment Summary: A few commenters recommended specific modifications to the HAI infection list. One commenter requested the removal of hemodialysis catheter/port related infections. This commenter also noted that antibiotic use predisposes patients to Clostridioides difficile so C. Diff should not be included in the measure. Another commenter suggested removing "Unknown site and unknown bugs" because this diagnosis does not provide actionable information to the SNF. This comment recommended only including known conditions with known incubation periods and known prevention and treatment approaches.

Response: Thank you for sharing recommendations for measure modification. We acknowledge the concerns about attribution between dialysis centers and SNFs. We would like to point out that dialysis utilization is controlled for in risk adjustment in two ways, using revenue center codes for dialysis on the prior proximal IP claim and HCC134 in the past year. In response to the comment on antibiotic use and C. Diff, we recognize this issue and will take your comment into future consideration and continue to evaluate the appropriateness of including C. Diff in the SNF HAI measure. However, we generally believe that C. Diff is a manageable condition and there are several strategies to prevent C Diff.[6] We would like to note that C. Diff typically does not require hospital care unless the SNF is unable to control it. We also believe that SNFs should be able to account for the higher likelihood of infections resulting from the use of certain drugs such as antibiotics. Regarding unknown site and unknown bugs, although the condition is unknown, it still speaks to the quality of care received in the SNF. So long as the SNF resident is sick enough to require hospitalization and meets the requirements of the SNF HAI definition, the infection should be counted.

Comment Summary: One commenter asked if the SNF HAI measure will differentiate between CAUTI and other UTIs.

Response: Thank you for your question. The measure includes several diagnosis codes for UTI and CAUTI. However, it does not distinguish between the infection types. The SNF HAI measure counts all HAIs attributable to the SNF and does not calculate different scores for different types of infections.

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[6] *Strategies to Prevent Clostridioides difficile Infection in Acute Care Facilities | CDC*. (n.d.). Retrieved November 30, 2020, from https://www.cdc.gov/hai/prevent/cdi-prevention-strategies.html

2.2.3 HAI Identification

Comment Summary: A number of commenters criticized the use of diagnosis codes for HAI identification and contended that claims data is inappropriate for capturing HAIs. The primary concern is that diagnosis information from the IP setting could be inaccurate and incomplete. Commenters explained that standard diagnostic criteria have not been established in the IP setting, making diagnosis codes prone to upcoding or other errors and creating inconsistencies in coding. Many commenters cited that UTI and sepsis are often incorrectly identified in claims. In particular, one commenter had strong objections to the use of claims data due to low reliability in predicting health outcomes and referenced a CMS study as a source of evidence.

These commenters asserted that data from medical records or use of confirmatory lab tests would be more accurate than claims. Commenters had several different recommendations such as use of revised McGeer criteria, alignment with NHSN surveillance protocols, increase NHSN enrollment, and alignment with the National Action Plan to Prevent Healthcare-Associated Infections. One commenter requested that CMS enforce use of clinical standards for diagnosis. Another commenter suggested removing unspecified sepsis from the HAI code list.

Response: Thank you for sharing your concern and proposing recommendations. We recognize the possibility of upcoding in IP claims. However, upcoding of infections should not affect the measure score because exact identification of infection is not relevant to the accuracy of the HAI rate. The upcoding of the specific diagnosis code on the IP claim is less important provided the claim correctly identifies the condition as an HAI. For example, differentiating between stroke and UTI is important for accurate calculation of the HAI rate, whereas differentiating between sepsis and UTI is less important because both are HAIs. It is highly unlikely that the hospital would omit coding an infection.

In response to the commenter's evidence that administrative claims data are unreliable for HAI monitoring, we assume that the commenter is referring to the report, Accuracy of Coding in the Hospital Acquired Conditions–Present on Admission Program (the commenter did not share citation).[7] This study conducted a medical record review to calculate the accuracy of hospital

[7] Cafardi, S. G., Snow, C. L., Holtzman, L., Waters, H., McCall, N. T., Halpern, M., Newman, L., Langer, J., Eng, T., & Guzman, C. R. (2012). *Accuracy of Coding in the Hospital-Acquired Conditions-Present on Admission Program Final Report*. https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitalacqcond/downloads/accuracy-of-coding-final-report.pdf

code of Hospital Acquired Conditions (HAC) and Present on Admission (POA) conditions. Contrary to the commenter's claim, this study did not find patterns of widespread under-reporting of HACs or over-reporting of POA status. Rather, the study found that only 3% of HAC cases were underreported and 91% of all cases coded POA were coded accurately. Another medical record review study, conducted by RTI and CMS, assessed the accuracy of the principal diagnosis coded on a Medicare claim to identify whether a patient was admitted for a diagnosis included in CMS's list of potentially preventable readmission (PPR) diagnoses.[8] The study analyzed inpatient discharges from October 2015 through September 2017 and found high agreement between principal diagnoses in Medicare claims and corresponding medical records. Specifically, the agreement rate between principal diagnoses in Medicare claims and information in the corresponding medical records ranged from 83% to 94% by study hospital and the 91% to 97% of principal diagnoses from the corresponding medical records were included in CMS's list of PPR diagnoses.

As outlined in the TEP Summary Report, TEP members also voiced similar concerns about the accuracy of inpatient claims to accurately capture infections acquired in a SNF. However, the TEP discussed that alternative data sources (i.e., adding items to the MDS or NHSN enrollment) would increase provider burden and that MDS data was prone to manipulation. The TEP ultimately agreed that claims data were of high quality and would strengthen the SNF QRP measure portfolio without increasing burden.[9] We believe this issue merits further investigation and we will continue to evaluate data sources in future re-specifications.

Comment Summary: Multiple commenters supported the proposed HAI incubation window and commended the alignment with NHSN standards.

Response: Thank you for your comments, we appreciate your support.

Comment Summary: Several commenters had objections to the proposed HAI incubation window. These comments asserted that the proposed time window is not reflective of the clinical events involved with an HAI. Some of the commenters believe that applying one time window for all HAIs is inaccurate since infections have varying incubation windows. Others were concerned that the start of the infection window (day four of the SNF stay) is too early in the stay to attribute HAIs to SNF for infections with long incubation periods. Commenters cited examples of infections with lengthy incubation: hepatitis B and C, pyelonephritis, respiratory

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[8] He, F., Daras, L. C., Renaud, J., Ingber, M., Evans, R., & Levitt, A. (2019, June 3). *Reviewing Medical Records to Assess the Reliability of Using Diagnosis Codes in Medicare Claims to Identify Potentially Preventable Readmissions* https://academyhealth.confex.com/academyhealth/2019arm/meetingapp.cgi/Paper/31496

[9] Refer to Footnote 3

syncytial virus, and COVID-19. One commenter requested full testing on different possible start dates.

Response: Thank you for the comment. The SNF HAI measure obtained clinical input from TEP panelists about the time window to identify HAIs attributed to the SNF. The TEP agreed that the same time window should be applied to all infections and that three days was appropriate. The selected incubation window may not hold true for all infections, but it is a reasonable average. We believe that the gains in measure simplicity from using a single incubation window outweighs the small loss in measure accuracy. We also note that the HAI measure excludes chronic infections and infections that typically take a long period of time to present (e.g., typhoid arthritis). See sections 3.3.1 and 3.3.2 of the TEP Summary Report for details.[10]

Comment Summary: One commenter observed that the HAI incubation window in the SNF HAI measure does not align with the HAI window defined in the NHSN guideline. This commenter noted that in the NHSN guideline, an infection is considered "Present on Admission" up to 48 hours after admission (infection is attributable to the previous facility) and an HAI on or after the third calendar day of admission (infection is attributable to the current facility). In contrast, the SNF HAI measure counts HAIs starting on fourth day after admission. The comment asked for clarification regarding this discrepancy in attribution and asked CMS to carefully describe the Present on Admission (POA) and HAI definitions. The commenter suggested the use of a table or figure to depict the attribution timeline.

Response: Thank you for this observation and your careful review of the HAI incubation window. According to the NHSN guidelines, if the date of event of the NHSN site-specific infection criterion occurs between 2 days before admission and the calendar day after admission, then the infection is considered as Present on Admission (POA) and it is not an HAI.[11] If the date of event of the NHSN site-specific infection criterion occurs on or after the 3rd calendar day of admission, then it is an HAI.

The NHSN POA timeline is not directly applied in the SNF HAI measure and the HAI timeline differs slightly from the NHSN guidance. As described in the Draft Measure Specifications, the HAIs are identified using both the principal diagnosis code and the Present on

[10] Refer to Footnote 3

[11] Refer to Footnote 1

Admission (POA) indicator on the re-hospitalization claim.[12] In IP claims coding, the Present on Admission indicator is applied if the conditions are present at the time the order for inpatient admission occurs. The POA indicator is intended to differentiate conditions present at the time of admission from those conditions that develop during the inpatient admission. The hospitalization must occur during the period beginning on day four of SNF admission and within three days after SNF discharge.[13]

We acknowledge that the SNF HAI differs from the NHSN timeline. The incubation period for the SNF HAI measure is more liberal than the NHSN timeline and gives SNFs an extra day before starting the attribution timeline. NHSN HAI starts *on* day three of admission, whereas SNF HAIs starts *after* day three of admission. The incubation window is extended by one day for the SNF HAI measure to accommodate the use of claims as the data source. Another difference is that the SNF HAI measure applies the post-discharge attribution window using a three day timeline. The NHSN timeline does not use a post-discharge attribution window. See Table 1 for a detailed example of the HAI incubation window.

Table 1: Incubation Timeline for SNF HAI Measure

Setting	Days	HAI Window	Classification
SNF Stay	Day 1 - Admission	3-day window from SNF Admission	
	Day 2		
	Day 3		
	Day 4	Start of HAI attribution to the SNF	HAI
	Day X		
	Day 21 - Discharge		
Community	Day 1	3-day window from SNF Admission	
	Day 2		
IP Stay	Day 1 - Admission		
	Day 2	End of HAI attribution to the SNF	
	Day 3 -Discharge		

2.2.4 Risk Adjustment

Comment Summary: Many commenters agreed that the measure should be risk-adjusted. CMS received general support for the risk adjustment approach and selected risk factors.

[12] Refer to Footnote 2

[13] Refer to Footnote 2

Response: We thank you for your support and appreciate your engagement in measure development.

Comment Summary: Some commenters considered the proposed risk adjustment approach as inadequate. These commenters believed that the list of variables for risk adjustment is incomplete and recommended adding several risk factors, such as: long-term care facility stays prior to the initial hospital admission, community infection rates for specific infection types, cognitive impairment, social factors (e.g., SES), provider-level factors (e.g., staffing), hospital-specific factors, and special populations such as HIV/AIDS, psychiatric diagnoses, traumatic brain injury, Huntington's Disease, and ventilator use.

Response: Thank you for reviewing the risk adjustment methodology and sharing your feedback. Many of the suggested variables are included in risk adjustment. The risk adjustment model accounts for comorbidities on prior short-term claims in the past year using Hierarchical Condition Categories (HCC) software version 22 and principal diagnosis clinical category on the prior proximal IP stay using Clinical Classification Software (CCS). For example, special populations are accounted for using HIV/AIDS (HCC1), Parkinson's and Huntington's Diseases (HCC78), Schizophrenia (HCC57), Major Depressive, Bipolar, and Paranoid Disorders (HCC58), Coma, Brain Compression/Anoxic Damage (HCC80), Severe Head Injury (HCC166), Major Head Injury (HCC167). Cognitive impairment is accounted for using Delirium dementia and amnestic and other cognitive disorders (CCS 653) and Parkinson's and Huntington's Diseases (HCC78). Regarding provider-level factors, SNF HAI risk-adjustment is implemented via a hierarchical logistic model. The hierarchical modeling approach allows for a provider-specific effect, which accounts for clustering of patients within the same facility and captures variation in the measure outcome across SNFs. This provider-specific intercept helps isolate the differences in measure performance that are due to provider-specific behavior and characteristics. See the Statistical Risk Model and Variables section in the Draft Measure Specifications for detailed risk adjustment methodology.[14]

As for the suggested risk adjustment factors that are unaddressed in the proposed model, we will take your comments into future consideration. We will continue to test and evaluate the risk adjustment methodology. In terms of social factors, past National Quality Forum (NQF) guidelines stated that social risk factors should not be included as adjustment variables. However, the issue is being reconsidered and evaluated. NQF is conducting a social risk trial to

[14] Refer to Footnote 2

further investigate social risk factors in outcome measures.[15,16] We will monitor the results from this NQF trial and update our approach to social risk factors based on changes to the NQF guidelines.

2.2.5 Clarification

Comment Summary: A few commenters noted the lack of detail in the Draft Measure Specifications. These commenters thought that the Draft Measure Specifications did not contain an adequate explanation of the measure methodology to offer constructive comment. In particular, one commenter requested more detail on the calculation of the expected number of HAIs in the denominator, risk adjustment variables, and the risk adjustment model. Another commenter asked CMS to share the complete methodology in order to replicate the rate internally for continual process improvement at the facility level with concurrent data.

Response: Thank you for your feedback. We acknowledge your concerns and will consider releasing a full methodology report in the future.

2.3 Measure Implementation

2.3.1 Unintended Consequences

Comment Summary: A few commenters expressed concern that the measure will have negative consequences on patient care and provider burden. Commenters warned that the measure could potentially lead to an increase in SNF transfer time from IP to SNF and could either decrease SNF length of stay and increase early readmissions or alternatively delay and reduce transfers to hospital. Commenters also worried about potential unintended consequences such as an increase in inappropriate antibiotic use, deterioration of hospital relationships due to late, incomplete, or inaccurate IP diagnosis, and selective enrollment of healthy patients and denial of admission for high-risk residents. Additionally, facilities may elect to do screening cultures to identify presence of organisms on admission.

Response: Thank you for your thoughtful comments on unintended consequences. We expect providers to continue to exercise proper clinical judgement and plan care based on the patient's clinical needs. That being said, the measure is risk-adjusted to mitigate providers'

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[15] National Quality Forum (NQF). (2017). *Evaluation of the NQF Trial Period for Risk Adjustment for Social Risk Factors*. http://www.qualityforum.org/Publications/2017/07/Social_Risk_Trial_Final_Report.aspx

[16] National Quality Forum (NQF). (2018). *Social Risk Trial FAQ*. http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=87811

incentive to selectively enroll residents, transfer residents to hospitals early, or reduce or delay necessary IP transfer. If implemented, this measure will be monitored to identify unintended consequences including length of stay, transfer, and patient selection patterns, which could lead to future re-specification of the measure as needed. Regarding the increased need for screening cultures, we recognize the cost and time of obtaining cultures, but we also expect SNFs to meet the current standards of care to prevent and manage HAIs. If the purpose of performing cultures during patient admission review is to screen for HAI from hospitals, we would like to emphasize that the SNF HAI measure implements precautions to prevent misattribution. The SNF HAI measure excludes infections acquired from the prior IP stay by starting HAI identification on day four of the SNF stay and applying the RIT to omit repeat infections. Refer to our response to attribution comments in subsection 2.1.3 of this report or refer to the Draft Measure Specifications for more information.[17]

We disagree that this measure will inadvertently incentivize antibiotic use. Unnecessary use of antibiotics is a major contributor to antibiotic resistance and HAIs. Antibiotic stewardship, which promotes effective and proper use of antibiotics, is critical to HAI prevention. We would also like to note that this measure has been developed to be used in concert with all SNF QRP measures in a way that mitigates unintended consequences. For example, existing readmission quality measures create disincentives for readmissions; so SNFs should be less inclined to shorten SNF stays and transfer residents to hospitals early in order to avoid HAI attribution.

2.3.2 Measure Endorsement

Comment Summary: One commenter expressed concern that SNF HAI measure is not endorsed by a consensus organization such as the National Quality Forum (NQF). This comment advocated for use of NQF-endorsed measures as the NQF process includes a robust measure review with routine measure maintenance to reflect changes in performance.

Response: We appreciate your input. Under 1899(e)(2)(B) of the Act, CMS has the legal authority to implement non-endorsed quality measures in SNF QRP. However, we agree that there is value in measure endorsement so we plan to submit the measure for NQF endorsement in the future. While the measure currently does not have NQF endorsement, it has been fully tested. We believe the measure is sufficiently reliable and valid to submit to the Measures under Consideration (MUC) list for SNF QRP. We will consider releasing full testing results in the future. We will seek public input from the National Quality Forum's Measure Applications

[17] Refer to Footnote 2

Partnership (MAP) Post-Acute Care/Long-Term Care Workgroup during the annual in-person meeting in January 11, 2021.

2.3.3 Measure Testing

Comment Summary: One comment stated that risk adjustment should have been tested and finalized prior to entering a comment period and pre-rulemaking. This commenter was concerned that CMS is determining standards for quality measures without baseline data on HAIs in SNFs. Specifically, the commenter raised concerns that the preliminary study was done with a very limited sample, which is insufficiently representative of the SNF population.

Response: Thank you your comment. The measure has been fully tested for reliability and validity. Contrary to the commenter's claims, we did not develop the SNF HAI measure on a limited sample. We performed testing on a study population of SNFs with at least 25 eligible stays using one year of data. This study population includes 14,347 SNFs, which represents 85.90% of Medicare certified SNFs in FY 2018. As for baseline HAI rates, our analyses found that in FY 2018 the mean risk-adjusted HAI rate among SNFs with at least 25 stays was 6.15% (median: 5.85%, IQR: 4.91%-7.08%). The risk-adjusted HAI rate among reportable SNFs ranged from a minimum of 2.19% to a maximum of 19.83%. For reliability and validity testing, we conducted the following: 1) split-half testing to assess the internal consistency of the measure, 2) model fit analysis to determine if the HAI model can accurately predict HAI cases while controlling for differences in resident case-mix, and 3) correlation analysis between the HAI measure and other publicly reported quality measures to assess convergent validity. We will consider releasing full testing results in the future. To address the commenter's concern about how standards for HAI quality are determined, we would like to clarify that HAI performance is based on peer comparison. SNFs are assigned to a performance category by comparing the facility's 95% interval estimate of its risk-adjusted HAI rate to the national observed HAI rate. The methodology for calculating 95% interval estimates is described in the dry run reports.

2.3.4 Public Reporting

Comment Summary: A few commenters supported the TEP's recommendation of providing quarterly reports via CASPER. These commenters advocated for timely feedback on HAI performance.

Response: We thank you for your recommendations on public reporting. The SNF HAI measure will be proposed as an annual measure. Therefore, it will be reported on a yearly basis instead of quarterly. We will take your comment into future consideration and will evaluate the option of reporting on a quarterly basis.

Comment Summary: One commenter recommended timely availability of patient-specific data reports. This commenter felt that the SNF HAI dry run report was not very useful because SNFs are unable to differentiate which patient caught which infection. Likewise, the lack of patient-level information makes it difficult to validate the report for accuracy. This commenter suggested that patient-level data will improve usability of the provider reports for quality improvement activities.

Response: Thank you for sharing your recommendation. The measure is designed as a facility-level risk-adjusted score, not a patient-level score. Therefore, reporting of the SNF HAI measure will be provided at the facility-level. The quality measure score is intended to provide a summary picture of overall performance in HAI prevention and control. We believe that reporting a facility-level score is valuable because it informs SNFs of their overall HAI rates and allows them to compare these rates to their peers, which will enable SNFs to track their performance and improve their quality of care.

2.3.5 HAI Prevention

Comment Summary: Some comments noted that SNFs do not have resources for quality improvement and had various recommendations for how CMS can support HAI prevention in SNFs. One commenter asked CMS to consider supporting HAI prevention in SNFs by implementing something similar to CMS's Hospital Innovation and Improvement Networks. Another commenter requested CMS address barriers such as the lack of standardization of infection diagnoses and management in SNFs and across settings as well as the deficiencies in provider training as part of its plan to effectively implement this measure. A different commenter observed that clinical analytics technologies are not widely used in SNFs. This commenter urged CMS to explore policy options to incentivize SNFs to adopt clinical surveillance technology to reduce and prevent HAIs.

Response: We thank you for sharing your concern about resources for HAI prevention. We would like to emphasize that SNFs should already establish and maintain infection control programs in order to meet the quality requirements for certification in the Medicare program as outlined in the Conditions of Participation. CMS has made several resources available such as free online training modules in partnership with the CDC and Quality Improvement Organizations (QIO).[18] The QIO program aims to increase patient safety, coordinate care, and improve clinical quality by utilizing collaborative networks.

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[18] *Infection Prevention Training | LTCF | CDC*. (n.d.). Retrieved November 30, 2020, from https://www.cdc.gov/longtermcare/training.html

2.3.6 Impact of COVID

Comment Summary: Several commenters urged CMS to consider the impact of the COVID-19 crisis on SNFs. COVID-19 disrupted patient care and resulted in a decrease in preventive care. These commenters reasoned that since COVID-19 is a worldwide pandemic with high community transition, SNFs should not be held solely responsible for COVID transmission and penalized for it. A few comments asked that the measure be delayed until after the PHE has expired.

Response: Thank you for sharing your concerns. We acknowledge the severity of the pandemic and its detrimental impact on SNFs. We note that no data reflecting services provided from January 1, 2020 through June 30, 2020 will be used in measure calculations, as we recognize that quality data collection and reporting for services furnished during this time period may not be reflective of their true level of performance during this time of emergency. At the same time, COVID-19 has heightened the importance of infection prevention and control programs and the need for HAI data. Evidence suggests that higher COVID-19 transmission in healthcare settings is associated with poor infection control, staff rotations between multiple SNFs, and inadequate patient COVID-19 screenings.[19,20] We will continue to evaluate our options and explore the impact of COVID-19 on quality reporting as the pandemic evolves.

2.3.7 Medicare Quality Reporting Programs

Comment Summary: A couple of commenters expressed concerns that SNFs will be penalized multiple times for the same case due to competing and similar quality measures. Another commenter asked if preventative measures will pay for reporting. These commenters also asked if quality measures will adjust for COVID-19 such as changes in benchmarks.

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[19] Kimball, A., Hatfield, K. M., Arons, M., James, A., Taylor, J., Spicer, K., Bardossy, A. C., Oakley, L. P., Tanwar, S., Chisty, Z., Bell, J. M., Methner, M., Harney, J., Jacobs, J. R., Carlson, C. M., McLaughlin, H. P., Stone, N., Clark, S., Brostrom-Smith, C., … Zane, S. (2020). Asymptomatic and Presymptomatic SARS-CoV-2 Infections in Residents of a Long-Term Care Skilled Nursing Facility — King County, Washington, March 2020. *MMWR. Morbidity and Mortality Weekly Report*, *69*(13), 377–381. https://doi.org/10.15585/mmwr.mm6913e1

[20] McMichael, T. M., Clark, S., Pogosjans, S., Kay, M., Lewis, J., Baer, A., Kawakami, V., Lukoff, M. D., Ferro, J., Brostrom-Smith, C., Riedo, F. X., Russell, D., Hiatt, B., Montgomery, P., Rao, A. K., Currie, D. W., Chow, E. J., Tobolowsky, F., Bardossy, A. C., … Harney, J. (2020). COVID-19 in a Long-Term Care Facility — King County, Washington, February 27–March 9, 2020. *MMWR. Morbidity and Mortality Weekly Report*, *69*(12), 339–342. https://doi.org/10.15585/mmwr.mm6912e1

Response: The SNF QRP is a pay for reporting program and there is no additional burden nor penalty on SNFs for the reporting of this claims-based measure. As noted above, no data reflecting services provided from January 1, 2020 through June 30, 2020 will be used in measure calculations, as we recognize that quality data collection and reporting for services furnished during this time period may not be reflective of their true level of performance during this time of public health emergency due to the COVID pandemic.

3 OVERALL ANALYSIS AND RECOMMENDATIONS

3.1 Overall Analysis of Comments

The majority of commenters agreed with the measure's importance and believed that a well-designed measure can improve prevention and management of HAIs in SNF. Several commenters supported the proposed measure specification such as the use of administrative data for HAI identification, the restriction to HAIs severe enough to require inpatient hospitalization, and the alignment with the NHSN HAI timeline. Other commenters, however, were critical of the data source, HAI definition, and selected variables for risk adjustment. These commenters objected to the use of inpatient diagnoses codes due to inaccuracies in coding and raised concerns that some of the included infection types for HAI were out of scope for SNFs and that risk adjustment is inadequate. CMS also received some comments about measure implementation. A few commenters were concerned about implementing the measure during a global pandemic and were concerned about the measure's unintended consequences, lack of NQF endorsement, and interaction with other quality measures. We provide verbatim text of all public comments received in Appendix A.

3.2 Preliminary Recommendations and Next Steps

CMS and Acumen appreciates the comments received for the SNF HAI measure. We thank all commenters for sharing their support, concerns, questions, and recommendations. We will consider comments in future measure development and evaluation efforts.

APPENDIX A: PUBLIC COMMENT VERBATIM REPORT

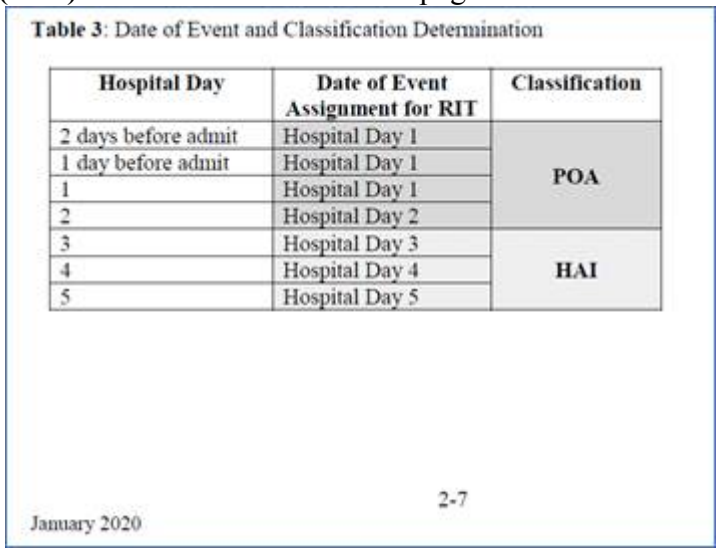
Appendix A.1 contains the verbatim texts of the comment received. The information is provided in table format and presented in order of submission number. The table presents the name, affiliated organization, as well as the submission number and the date of submission. The submission number is the assigned identification number for the comment. The date is when the email was received in the QM-Public-Comment@acumenllc.com inbox. The submitter name for each comment is the name of the person who signed the letter. For some comment submissions, the person who signed the comment letter is not the same as the person who submitted the comment nor the same as the contact person provided in the comment.

Please note that the verbatim text has been edited to improve the readability of this report. We omitted letter template details (i.e., company logo) and did not include attachments. We removed the cross-reference feature of citations and converted citations from footnotes that are listed at the bottom of the page into citations that are listed at the end of the comment.

A.1 Verbatim Comments and Responses

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
1	9/16/2020	Bobbie Weber MSN, RN MDS Coordinator/ADON	Manilla Manor	Will this differentiate between CAUTI and other UTI
2	9/16/2020	Stacy Perry, RN, BSN RNAC / Case manager	Sarah Reed Senior Living	Good afternoon- Without sounding harsh or unprofessional, the fact that you are even considering putting this measure into place during a global pandemic is unbelievable. This LTC industry is getting crazier and crazier by the day. Thank You.
3	9/21/2020	Lee Gao Manager of Auditing Department	Hong Kong IP Limited	Dear Principal, Nice day. We are an organization specialized in dealing with Trademark Registration and Internet Copyright dispute in Asia. Yesterday, one company named Clarkson Investment Co. Ltd applied for the Chinese Trademark "acumenllc" with us. After checking, we found it's your company name. Did you consign that company to register this Trademark ? Or are they your subbranch? Because this is very important, pls give us a reply ASAP. Best Regards
4	9/28/2020	DeAnn Walters Director of Clinical Affairs	Individual	These comments are my own and not a comment for the organization that I work for. As an administrator for 20 years, I have seen acute care hospitals code infections as the DRG for residents that should not have included the coding. The hospital provides diagnostic tests for

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
				individuals that are not in alignment with the reason for hospital care and then code that as part of the stay. This coding allows the hospital to receive additional payment and so using this claims based measure would negatively reflect on my nursing home depending on the hospital to which I have had to discharge my resident not based on the actual reason for the hospital stay or the excellent care the resident had been provided. Also, elders, which mostly reside in skilled nursing homes, tend to have, as an example, a UA that reads high enough to be considered a UTI but has none of the signs and symptoms. This would then be reflected publicly as an infection when it does not meet the criteria that a nursing home must use to determine a UTI based on the RAI guidance. This misrepresentation would be used against skilled nursing to say that nursing homes are hiding infections when the case is they are just two very different measures. By using the claims based data it would erroneously reflect a higher infection level than what is the reality. This measure would not inform factual information to the public nor for quality purposes. Thank you for your consideration.
5	9/29/2020	Laurie Laxton, RN, BSN, CCFA, RAC-CT, IP-BC Clinical Education Program Lead	Ability	Hello, I have queried several colleagues and we all have the same question. Would CMS please carefully define the timeline for Present on Admission vs Healthcare Acquired Infection in a Skilled Nursing Facility? Per the Final Technical Expert Panel Summary Report page 13- **3.3.2 Operational Definition: Time Window "The TEP strongly favored aligning the measure with the Center for Disease Control and**

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
				Prevention's National Healthcare Safety Network (NHSN) time window for HAIs, which would make infections attributable to the SNF starting on the fourth day after admission and ending 3 days after discharge." Per the document **Identifying Healthcare-associated Infections (HAI) for NHSN Surveillance:** page 7 **Table 3:**  **Table 3**: Date of Event and Classification Determination 2-7 January 2020 and states "An infection is considered a Healthcare-associated Infection (HAI) if the date of event of the NHSN site-specific infection criterion occurs on or after the 3rd calendar day of admission to an inpatient location where day of admission is calendar day 1." The TEP stated they wanted to follow the current CDC/NHSN timeline definition, but as is seen in this table above, Present on Admission includes only 48 hours after admission and HAI begins starting the **THIRD** day after admission. Yet per the SNF QRP HAI proposed measure and the TEP final statement they include up to day 3 after admission as being credited to the previous institution and

Hospital Day	Date of Event Assignment for RIT	Classification
2 days before admit	Hospital Day 1	POA
1 day before admit	Hospital Day 1	
1	Hospital Day 1	
2	Hospital Day 2	
3	Hospital Day 3	HAI
4	Hospital Day 4	
5	Hospital Day 5	

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
				HAI's attributable to the SNF starting on the **FOURTH** day after admission. A table such as is stated above in the CDC document, clarifying the new SNF QRP measure and when SNF's need to consider an infection attributable to the previous institution or attributable to their building would be greatly appreciated. Thank you for your time, Laurie Laxton
6	10/2/2020	Jutanna Fulbright, RN, MSN, ACM System Director Clinical Quality Analytics	Covenant Health	We appreciate the effort to keep our most vulnerable residents safe and to give the public a measurable metric for patient care. The risk adjusted HAI rate will allow for comparison with other facilities. This tool will be more useful if the complete methodology is shared in order to replicate the rate internally for continual process improvement at the facility level with concurrent data. In review of the proposed SNF HAI measure we do have the following concerns. The measure creates a scenario in which the skilled facility will be dependent on the accuracy and completeness of the acute care facility's coding for both the index admission and subsequent readmission for the patient in the event of infection. Due to this dependence, increased time will need to be devoted to the preadmission review to identify any coding opportunities prior to SNF transfer. The expected additional time burden will create a lag in transfer times to skilled facility which will have a ripple effect for acute care facilities possibly extending their length of stay. A more narrowed focus on SNF acquired infections would allow the facility to drill down to process issues and implement process improvement measures. Skilled facilities will be attributed an HAI that may have been present before day 3 but due to failed treatment required readmission to acute care for more intense treatment. This could create a scenario in which

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
				skilled facilities feel pressured to readmit to acute care sooner to avoid the HAI, or keep a patient at their facility in an attempt to treat the condition either of which would not be in the best interest of the patient. The addition of this measure will impact health care systems with both acute care hospitals and skilled facilities in multiple quality programs. Cases that are included in this proposed measure may also be included in other SNF and Hospital quality measures which would penalize the facilities multiple times for the same case.
7	10/13/2020	Kathleen Rice Quality Improvement Specialist Population Health Organization UC San Diego Health	Individual	Dear CMS Quality Team, I am writing in hopes there will be an adjustment to the Medicare Stars and ACO quality metrics to reflect the challenges and opportunities the Coronavirus pandemic has created in healthcare. There has been no single greater health system challenge in recent history, yet as of now the 2020 ACO and Medicare quality measures have not changed to reflect any clinical prioritization based on Coronavirus or the fact that most health systems were not offering preventative care services for up to 4 months this year due to stay at home orders. Since there have been no adjustments to the measure sets can we expect that the preventative measures will be pay for reporting? Or that the benchmarks will be appropriately adjusted to reflect the current public health crisis? Thank you for your consideration. Best, Kathy Rice (commenting personally)
8	10/13/2020	Nancy Foster Vice President, Quality and Patient Safety Policy	American Hospital Association (AHA)	October 13, 2020 Lee Fleisher, M.D. Chief Medical Officer and Director of Center for Clinical Standards and Quality

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
				Centers for Medicare & Medicaid Services Hubert H. Humphrey Building 200 Independence Avenue, S.W. Room 445-G Washington, DC 20201 ***RE: Development of the Skilled Nursing Facility (SNF) Healthcare-Associated*** ***Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program (SNF QRP)*** Dear Dr. Fleisher, On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 750 hospital-based skilled nursing facilities (SNFs), and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services (CMS) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure. The AHA applauds the agency for continuing to develop new measures in efforts to keep patients safe and improve the overall quality of care. 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:

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				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 some 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.** 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.

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				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

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				"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

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				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.

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				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**

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				better patient outcomes. We suggest CMS scrap this measure and develop one that is timely and actionable. We thank you for the opportunity to comment on this quality measure. If you have questions concerning our comments, please feel free to contact me, or have a member of your team contact Akin Demehin, director of policy, at ademehin@aha.org. Sincerely, /s/ Nancy Foster Vice President, Quality and Patient Safety Policy
9	10/13/2020	Loretta Willis Vice President, Quality Advocacy, Research & Innovation and Post-Acute/Continuing Care	Healthcare Association of New York State (HANYS)	**Proposed: Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations for the Skilled Nursing Facility Quality Reporting Program** On behalf of our member nonprofit and public skilled nursing facilities and other healthcare providers, the Healthcare Association of New York State appreciates the opportunity to comment on ways to reduce healthcare-acquired infections, recognizing that these events are associated with longer lengths of stay, use of higher-intensity care and increased mortality. The proposed *SNF HAIs Requiring Hospitalizations* measure would estimate the risk-standardized rate of HAIs that are acquired during SNF care and result in hospitalization. SNF HAIs that are acquired during SNF care and result in hospitalization will be identified using the principal diagnosis on the Medicare hospital claims for SNF residents during the time window beginning on day four after SNF admission and within day three after SNF discharge. The measure would be risk adjusted to "level the playing field" to allow

Submission Number	Date	Submitter Name and Credentials	Submitter Organization	Comment Text
				comparison based on residents with similar characteristics between SNFs. While HANYS supports the development of measures to address core issues that are most vital to high-quality care and better patient outcomes, we believe this claims-based measure is flawed and fails to provide meaningful information for all stakeholders. In a recent National Quality Forum report[1], panel members said that the two- to three-year time lag for claims-based measures to be fully processed makes it difficult to make timely and meaningful improvements. HANYS' members have expressed the need for more timely information to make the data more relevant in their conversations with patients, leadership and internal staff. Additionally, the *SNF HAI Quality Measure Technical Expert Panel Report*[2] identified the potential for errors or inconsistencies in coding, which resulted in the decision to use acute care claims. Our SNF members have expressed concern that this approach would reflect performance calculated based on hospital information, not SNF information, and noted differences in hospital surveillance that may result in an inaccurate HAI rate. This creates a risk that the data would not reflect the current quality of care being delivered by the SNF, diminishing confidence in the use of this data for improvement purposes. Further, this measure is currently made up of 325 ICD-10 codes, which range from infections related to devices or stumps to skin infections, making it extremely difficult to effectively isolate and address performance issues. HANYS' members expressed concern that many of the infections included in this measure cannot be prevented or influenced by care received at the SNF. Additionally, infections in SNFs are known to trend to community infection rates. SNF residents may leave the facility for many reasons

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				and may acquire an infection while outside, and therefore should not be attributed to facility care or the lack thereof. We appreciate that this measure would be risk adjusted to level the playing field, but many patient and provider factors that influence outcomes are not incorporated into the measure's risk adjustment methodology. Additionally, the adjustment would be applied at the patient and hospital level, not at the SNF level, since the data source is acute care claims, making it difficult for stakeholders to determine where there is an opportunity for improvement. Lastly, recognizing that SNF personnel dedicated to infection control and prevention and quality improvement vary widely across New York state, in addition to "high-staff turnover, funding difficulties, and limited information technology (IT) access and infrastructure,"[3] we believe this approach would create an additional burden and may lead to an organization dedicating resources on areas other than those of the highest priority for patient care. **Recommendation** HANYS recommends CMS aligns HAI reduction efforts with the *National Action Plan to Prevent Healthcare-Associated Infections: Road Map to Elimination* priority areas: increase National Healthcare Safety Network enrollment and use NHSN surveillance protocols and resources to reduce urinary tract infections/catheter-associated infections and *Clostridium difficile* infection/multidrug-resistant organisms. Thank you for the opportunity to comment on this request for information. If you have any questions regarding our comments, please contact me at (518) 431-7716 or lwillis@hanys.org. Sincerely, 

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				Loretta Willis Vice President, Quality Advocacy, Research & Innovation and Post-Acute/Continuing Care Healthcare Association of New York State (HANYS) _____ [1] *MAP 2019 Considerations for Implementing Measures in Federal Programs: Post-Acute Care and Long-Term Care*; National Quality Forum, 2019. [2] *Final Technical Expert Panel Summary Report: Development of a Healthcare-Associated Infections Quality Measure for Skilled Nursing Facility Quality Reporting Program*; RTI International, 2019. [3] *National Action Plan to Prevent Health Care-Associated Infections: Road Map to Elimination* (p. 241); U.S. Department of Health and Human Services, 2013.
10	10/13/2020	Erin O. Vigne, RN, MA Director, Clinical Affairs	AMDA-The Society for Post-Acute Long-term Care	*October 13, 2020* AMDA-The Society for Post-Acute Long-term Care appreciates the opportunity to submit comments on the proposed healthcare-associated infections (HAIs) quality measure for the skilled nursing facility (SNF) Quality Reporting Program (QRP). AMDA is the only medical specialty society representing the community of over 50,000 medical directors, physicians and other practitioners working in post-acute and long-term care (PALTC) settings. While AMDA supports efforts to improve the quality of care delivered in the long-term care setting through QRP, this measure as proposed will create trends in several untoward consequences including overuse of antibiotics, increase in MDROs and a hesitation to transfer residents to the hospital for fear of penalties or poor quality measures. Therefore, after careful review of the proposal

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				outlining this SNF QRP measure, AMDA does not support it as drafted and does not recommend its adoption as presented. **Following are the issues that need resolution:** 1. <u>HAI determination is based on ICD-10 codes upon admission to the hospital</u>. In general, the definitions of HAIs are not readily estimated using administrative data. ICD-10 - codes can be grossly misleading and over coded. HAIs should not be defined by claims based criteria but instead with evidence-based revised McGeer or NHSN criteria, which assess infections in long-term care settings. o For example, sepsis is a frequently coded diagnosis in the emergency department and hospital in older adults upon admission. Yet only about half of patients coded for sepsis on discharge had an infectious organism attributing to the true infectious etiology.[1, 2] o In another example, for urinary tract infections (UTIs), the emergency department (ER) battery of tests include urinalysis, which picks up asymptomatic bacteriuria. Twenty-five to 50% of residents in nursing homes have asymptomatic bacteriuria, but many are coded as UTI in the ER and hospital due to abnormal urinalysis. A more reasonable approach would start from existing definitions that are grounded in evidence, agreed upon by experts, and already used in real-world settings. 2. The HAI score includes multiple types of infections, many of which are non-preventable.

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				○ Many of the infections listed in the ICD-10 codes inclusions (page 15) are not related to management of the patients in the post-acute setting; For example: • Infection due to devices or stumps includes infections unrelated to care in the nursing homes such as infection and inflammatory reaction due to implanted urinary neurostimulation device, infection and inflammatory reaction due to indwelling ureteral stent, infection of amputation stump. • Neurologic infections meningococcal meningitis or other bacterial meningitis. • Respiratory infections such as bronchiectasis with acute lower respiratory infection. • The measure also includes community-associated infections such as salmonella, shigella, viral encephalitis, etc. • Cellulitis ○ The current broad list of infections will also encourage the use of unnecessary antibiotics. For example, what can nursing homes do to reduce pansinusitis in their resident population? Our concern is that many residents will start getting unnecessary antibiotics as soon as they mention anything about nasal congestion, etc. A shorter, more targeted list of infections that we know are significant issues in nursing homes and that could be prevented if proper protocols are followed, would be far more effective.

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				3. The 4-day after SNF admission is not reflective of the clinical events involved with an HAI. o For example, the incubation period for some of the infections are longer than 4 days, e.g. Hepatitis B and C. o Another example is *Clostridioides difficile* infection. The definition and timing for hospital-onset, NH-onset and undetermined has been the focus of much research. o Another example: If a resident develops a wound at a hospital and comes to the NH for care for that wound, which later becomes infected with an MDRO, is that 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. Attributions of HAI gets more complex in short stay patients that this measure is being considered. There should be a narrow list of infections that have been shown through research to be preventable in the long-term care setting as there is a potential for many untoward consequences of the HAI measure as proposed. As discussed, the measure is not a true reflection of preventable HAIs and therefore is neither actionable but can also be erroneously punitive for the LTCF in the value based environment as this will be integrated into the measures used for NH Compare. In summary: 1. This may lead to LTCFs refusing admissions of more complex patients that have increased potential of infections

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				e.g. Bronchiectasis therefore causing the potential for limiting care options for patients. 2. This type of measurement is going to create a strong disincentive to appropriately transfer residents to acute care- thereby creating a potential for patient harm. 3. This measure will incentivize increase in inappropriate use of antibiotics leading to increase in antibiotic resistance, associate adverse effects and healthcare associated infections like C. diff. Thank you in advance for consideration of our input. *** [1] Fay, K., Sapiano, M. R. P., Gokhale, R., Dantes, R., Thompson, N., Katz, D. E., Ray, S. M., Wilson, L. E., Perlmutter, R., Nadle, J., Godine, D., Frank, L., Brousseau, G., Johnston, H., Bamberg, W., Dumyati, G., Nelson, D., Lynfield, R., DeSilva, M., … Epstein, L. (2020). Assessment of Health Care Exposures and Outcomes in Adult Patients With Sepsis and Septic Shock. *JAMA Network Open*, *3*(7), e206004. [2] *Comparison of Trends in Sepsis Incidence and Coding Using Administrative Claims Versus Objective Clinical Data*. (n.d.). Retrieved October 13, 2020, from https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4318944/ [3] *Urinary Tract Infection (UTI) Event for Long-term Care Facilities*. (n.d.). 10. https://www.cdc.gov/nhsn/PDFs/LTC/LTCF-UTI-protocol_FINAL_8-24-2012.pdf

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11	10/14/2020	Jodi Eyigor Director, Nursing Home Quality & Policy	LeadingAge	To: Acumen LLC From: Jodi Eyigor, Director, Nursing Home Quality & Policy Date: October 14, 2020 Re: Development of the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalization Measure for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) Thank you for the opportunity to comment on the development of this measure. LeadingAge supports the development of a healthcare-associated infections measure for the SNF QRP program and agrees with the specifications as outlined. Using claims-based data will provide a strong data source without creating additional burden for nursing home providers by requiring additional reporting through the Minimum Data Set (MDS) or other reporting method. LeadingAge supports narrowing the scope of claims to include only those for acute care transfers that required inpatient hospitalization to focus on the most severe healthcare-associated infections for which a certain stability and accuracy of diagnosis is assumed since any misdiagnoses would be corrected through the course of inpatient care. We support the utilization of an HAI time window that is consistent with the time window utilized by the Center for Disease Control & Prevention's (CDC's) National Healthcare Safety Network (NHSN) data, as this will not only provide clarity to support accurate reporting by providers, but also strengthens the measure by aligning with an existing, industry-accepted timeframe. Lastly, LeadingAge strongly supports the recommendation of Technical Expert Panel (TEP) to provide quarterly claims data to

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				providers through the Certification and Survey Provider Enhanced Reports (CASPER) application to give nursing homes timely feedback and data upon which they can base quality improvement. Thank you for your consideration and we look forward to the opportunity to provide future feedback should this measure be considered for long stay application.
12	10/14/2020	Daniel E. Ciolek, PT, MS, PMP Associate Vice President, Therapy Advocacy	American Health Care Association and National Center for Assisted Living (AHCA/NCAL)	October 14, 2020 Submitted electronically to: QM-Public-Comment@acumenllc.com Re: DRAFT MEASURE SPECIFICATIONS: SKILLED NURSING FACILITY HEALTHCARE-ASSOCIATED INFECTIONS REQUIRING HOSPITALIZATIONS FOR THE SKILLED NURSING FACILITY QUALITY REPORTING PROGRAM The American Health Care Association and National Center for Assisted Living (AHCA/NCAL) represents more than 14,200 long term and post-acute care facilities, or 1.07 million skilled nursing facility (SNF) beds and more than 260,000 assisted living beds. With such a membership base, the Association represents the majority of SNFs and a rapidly growing number of assisted living (AL) communities as well as residences for individuals with intellectual and developmental disabilities (ID/DD). We appreciate the opportunity to comment to the Centers for Medicare & Medicaid Services (CMS) and Acumen, LLC. team regarding the current status of your efforts to develop a claims-based quality measure of healthcare-associated infections (HAIs) for the SNF Quality Reporting Program (QRP). As part of its measure development process, on September 14, 2020, Acumen requested interested parties to submit comments on the candidate or concept measures that may be suitable for this project.

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				The recent challenges faced nationwide and worldwide with controlling the spread of the deadly COVID-19 virus have highlighted the importance of a systemic approach to implementing infection control measures both within the SNF as well as beyond the SNF walls. AHCA recognizes and supports the use of effective measures to prevent as well as control the spread of infections, especially those that have the most detrimental impact on the health of patients and at times, as in the case of communicable diseases, their caregivers. Several years ago AHCA/NCAL launched a Quality Initiative program that included measures to reduce hospital readmissions with current goals by 2021 of a reduction of readmissions by ten percent compared to Q1 2017 rates, or to maintain a rate of ten percent or less compared to the baseline period[1]. In addition, AHCA/NCAL offers an Infection Prevention Control Officer (IPCO) training certification course specially designed for healthcare professionals who desire to serve as Infection Preventionists (IPs) as established in the CMS Reform of Requirements of Participation for Long Term Care Facilities (required by November 2019)[2]. Most recently, AHCA/NCAL offers extensive infection control resources to help prevent the spread of COVID19 during the current public health emergency[3]. We believe that well-developed measures should provide accurate reflections of a provider's quality of care delivery for factors within their control. For example, the current worldwide COVID-19 pandemic has exposed just how critical the infection-specific incubation period can be before the onset of symptoms or positive infection test result is observed, and that in many cases, the patient was exposed to COVID-19 prior to the SNF admission. The measures should include mitigation approaches to prevent

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				inappropriate attribution of a HAI to the SNF in such cases. Additionally, the measures should have meaningful and traceable information necessary to permit root-cause analysis and other quality improvement activities by the provider for identified areas of suboptimal performance. Per the CMS comment solicitation AHCA understands the project objectives as follows: • Develop a healthcare-associated infections quality measure for the SNF QRP under the meaningful measure domain: Making Care Safer by Reducing Harm Caused in the Delivery of Care. • Specify the target population, including the exclusion criteria. • Identify risk adjustment variables and the approach for risk adjustment. • Gather feedback on the importance, feasibility, usability, and potential impact of calculating a HAI measure. • Identify additional guidance required for implementation in the SNF QRP. AHCA and member subject matter experts have reviewed the following key documents provided by the measure development team as well as other resources independently identified. • Draft measure specifications for the Skilled Nursing Facility (SNF) Healthcare Associated Infections (HAIs) Requiring Hospitalization[4]. • Final technical expert panel summary report: Development of a healthcare-associated infections quality measure for the skilled nursing facility quality reporting program, July 2019[5] In this letter the Association would like to focus on specific key topics discussed in the proposed SNF HAI measure. In general, our comments follow the flow and related section headings used in the draft measure specifications document.

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				If you have questions about any of our comments, please contact Daniel Ciolek at dciolek@ahca.org. Sincerely,  Daniel E. Ciolek Associate Vice President **AHCA Detailed Comments** **Target Population:** The target population identified for this proposed Healthcare-Associated Infections (HAI) measure are Medicare Fee-for-Service (FFS) beneficiaries. **AHCA Comment:** Our members appreciate the challenge in identifying quality performance for SNF residents for specific measures when SNFs provide services to both short-stay (primarily under Medicare-financed coverage) and long-stay residents (primarily under Medicaid coverage and private pay). We recognize that the SNF QRP program was designed to focus on care covered by Medicare post-acute care benefits, and that lack of availability of standardized quality data from Medicare Advantage (MA) enrollees receiving post-acute care severely limits the target population that can be included in most SNF QRP measures. However, due to the

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				relatively low incidence of HAIs identified in the proposed measure's numerator population, we are concerned that the continued growth in MA penetration and reduction of Medicare FFS enrollment may make this proposed measure unstable and less useful over the coming years. For example, the Medicare Payment Advisory Commission (MedPAC) March 2020 Report to Congress[6] states that *"Medicare FFS–covered SNF days typically account for a small share of a facility's total patient days"* and that *"Between 2017 and 2018, MA enrollment increased almost 8 percent while FFS Part A enrollment decreased slightly (–0.3 percent).* Additionally, the 2020 Medicare Trustees Report Table IV.C1 notes that in 2020, 39.9 percent of Medicare beneficiaries are enrolled in MA plans not included in the target population, and this percentage is projected to grow to 43.2 percent by 2029 further reducing the target population representation of the quality of Medicare covered post-acute SNF care[7]. Given this reality, we believe that the proposed measure name is a misnomer and should be revised to *"Skilled Nursing Facility (SNF) Healthcare-Associated Infections Associated with Fee-for-Service Stays Requiring Hospitalization"*. To label otherwise would be misleading to providers, consumers and policymakers. Another factor to consider is that, as reflected in a recent CMS SNF PDPM provider-specific impact file, the majority (60%) of the over 15,000 SNFs nationwide only have 1-10 total Medicare FFS admissions per month[8], meaning that minor fluctuations in infection prevalence could be inappropriately magnified in a measure with a shrinking denominator population. Additionally, the July 2019 *Final Technical Expert Panel Summary Report* environmental scan for this measure development project indicates that while HAIs in SNF are clinically important, their occurrence only represents approximately six percent of stays. With a baseline of low overall prevalence, and a

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				significant portion of SNFs currently having a low number of Medicare FFS admissions, as well as Medicare Trustee projections that this number will continue to decline, we are concerned about the long-term viability of a SNF HAI measure that only includes Medicare FFS beneficiaries in the target population. **Risk Adjustment Variables and Approach for Risk Adjustment:** Per the draft measure specifications document, CMS and Acumen, LLC. indicate that the proposed HAI measure does not have a simple form for the numerator and denominator because the risk adjustment is incorporated into the measure calculation rather than applied after the observed rate is calculated. The purpose of risk adjustment is to account for risk factor differences across SNFs, when comparing quality of care between them. In other words, the measure developers claim that the proposed risk adjustment *"levels the playing field"* and allows for fairer quality-of-care comparisons between SNFs by controlling for differences in resident case-mix. Risk adjustment is particularly important for outcome measures because resident outcomes may be determined by factors such as age, gender, and health status that go beyond the quality of care delivered by SNFs. **AHCA Comment:** The consensus of AHCA member subject matter experts is that adequate risk adjustment is going to be the key for this measure to be fair. They voice concerns that the draft specifications for risk adjustment are incomplete and need to be revised. The following comments address specific components of the SNF HAI measure specifications outlined in the draft measure specification document.

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				Measure Type: AHCA members agree that a SNF HAI measure should be an "Outcome" measure to be meaningful and actionable. **Brief Measure Description:** AHCA members believe the description will need to be revised to account for concerns described below. **Numerator Statement and Details:** ***Measure Outcome (Unadjusted Numerator):*** CMS and Acumen, LLC. indicate that the proposed numerator is the number of stays with a HAI acquired during SNF care and results in an inpatient hospitalization. The hospitalization must occur during the period beginning on day four after SNF admission and within three days of SNF discharge. Emergency department visits and observation stays are excluded from the numerator. The HAI definition was developed with input from a Technical Expert Panel and subject matter experts with clinical expertise specific to infectious diseases and the SNF population. See *Appendix A Table 1*. (columns A – C) in the draft specifications document for the proposed list of HAI conditions. The HAI definition includes conditions selected based on the following conceptual criteria: • Infections that are likely to be acquired during SNF care and severe enough to require hospitalization (e.g., life-threatening methicillin-resistant Staphylococcus aureus infections) • Infections related to invasive (not implanted) medical devices (e.g., infections associated with catheters, insulin pumps, and central lines; infection of tracheostomy stoma) The HAI definition excludes infections that meet any of the following criteria:

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				• Chronic infections (e.g. chronic viral hepatitis B with or without delta-agent) • 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) • Sequela and subsequent encounter codes (e.g. sequelae of inflammatory diseases of central nervous system) • Codes that include "causing disease classified elsewhere" (e.g. meningitis in bacterial diseases classified elsewhere) • Codes likely to represent secondary infection, where the primary infection would likely already be coded (e.g. viral endocarditis, pericarditis, myocarditis or cardiomyopathy) • 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) • Pre-existing infections that fall within the Center for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) Repeat Infection Timeframe (RIT) of 14 days. The HAI measure applies a slight modification to the CDC NHSN's RIT. Rather than using the date of infection identification (i.e., lab diagnosis date) as Day 1, HAI uses the prior IP discharge date as Day 1 since discharge indicates clinical stability. See *Appendix A Table 1* (columns D and E) of the draft specifications document for conditions that are considered as pre-existing on the prior qualifying hospital claims when linked to the

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				principal diagnosis codes (column B) on the re-hospitalization claim The following categories of specific ICD-10 codes are listed in Table 1 of the draft measure specifications for inclusion in the numerator population: • Infections related to Devices or Stumps (25 unique ICD-10 codes) • Eye/ear infections (10 unique ICD-10 codes) • Gastrointestinal infections (51 unique ICD-10 codes) • Genito-urinary infections (13 unique ICD-10 codes) • Neurological Infections (22 unique ICD-10 codes) • Respiratory Infections (103 unique ICD-10 codes) • Sepsis (33 unique ICD-10 codes) • Skin Infections (37 unique ICD-10 codes) • Unknown site and unknown bugs (5 unique ICD-10 codes) **AHCA Comment:** AHCA member subject matter experts agree that the numerator should include infections that are likely to be acquired during SNF care and severe enough to require hospitalization as well as infections related to invasive (not implanted) medical devices. However, we are concerned with the following phrase within the proposed criteria *"The hospitalization must occur during the period beginning on day four after SNF admission…"* would apply to all identified SNF HAI infection ICD-10 codes uniformly. Residents newly admitted to SNFs for a Medicare FFS stay are at risk for infection related to surrounding community or acute hospital stay exposure to HAI's that may not present symptomatically during the first three days of the SNF stay due to lengthy incubation periods. Examples of a few that are included in Appendix A of the

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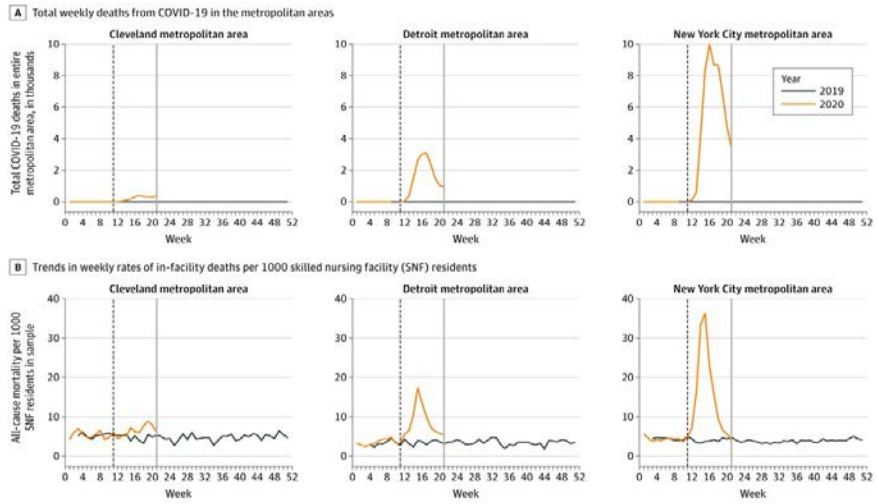
				draft specifications: Hepatitis B &C, pyelonephritis, and respiratory syncytial virus. Most recently, we are eight months into a worldwide COVID-19 pandemic, a virus that has been devastating to SNF residents, especially in hot-spot areas of the country where high community rates of infection have spilled over into local SNFs. For example, Barnett, et al (and other studies since) have reported a high correlation between community COVID-19 infection and death rates and those observed in SNFs in those communities (see figure below)[9].  We note the CDC currently states the following *"The incubation period for COVID-19 is thought to extend to 14 days, with a median time of 4-5 days from exposure to symptoms onset. One study reported that 97.5% of persons with COVID-19 who develop symptoms will do so within 11.5 days of SARS-CoV-2 infection."*[10] We note that the proposed SNF HAI measure draft ICD-10 codes for identifying SNF HAIs requiring hospitalization (Appendix A) includes the ICD-10 code U07.1 for confirmed cases of COVID-19.

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Other codes for suspected but to be confirmed cases of COVID-19 with lengthy incubation periods are also Listed in Appendix A.

The SNF post-acute population is already a high-risk population, frequently with multiple comorbidities. Exposure to risk factors including pathogens and virus that are outside the SNF providers control must be better accounted for in the proposed SHF HAI measure. In the absence of specific data from CMS and Acumen, LLC. to review, AHCA/NCAL evaluated
2018 hospital admission patterns for HAIs identified in the proposed measure specifications, including 62,389 directly from SNFs.

The table below highlights that 87 percent of the proposed HAI diagnoses that would be attributed to SNFs represent the Sepis and Respiratory Infections categories while the remaining seven categories represent between 0.01 to 6.33 percent of SNF HAI discharges to hospitals. Given the significant imbalance in frequency across the proposed SNF HAI categories, local swings in community infections rates of specific contagious pathogens with lengthy incubation periods not accounted for in the measure specifications could severely skew performance rates for SNFs located in such communities during the measure performance window.

<table>
<tr><th>Draft SNF HAI Category</th><th># Hospital Claims</th><th># Entered From SNF</th><th>% From SNF</th><th>% Across SNFs</th></tr>
<tr><td>Ear/eye infections</td><td>466</td><td>7</td><td>1.50%</td><td>0.01%</td></tr>
<tr><td>Gastrointestinal infections</td><td>23,865</td><td>1,117</td><td>4.70%</td><td>1.79%</td></tr>
<tr><td>Genito-urinary infections</td><td>16,026</td><td>460</td><td>2.90%</td><td>0.74%</td></tr>
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Infections related to devices or stumps	27,195	2,559	9.40%	4.10%
Neurological infections	1,528	22	1.40%	0.04%
Respiratory infections	345,470	17,004	4.90%	27.25%
Sepsis	450,574	37,219	8.30%	59.66%
Skin infections	157,695	3,949	2.50%	6.33%
Unknown site and unknown bugs	2,518	52	2.10%	0.08%

We suggest that the measure replace the fixed day-four from SNF admission inclusion window for numerator population, regardless of ICD-10 diagnosis, with condition-specific inclusion windows that better account for lengthy incubation periods so that the majority of ICD-10 codes included in the numerator population most likely reflect infections related to SNF infection control practices and not patient community exposure or hospital practices prior to the SNF admission.

An additional concern AHCA provider subject matter experts have regarding the list of draft ICD-10 codes for inclusion in the numerator population are the five ICD-10 codes listed under the category *"Unknown site and unknown bugs"*. We do not believe the inclusion of "unknown" conditions should be attributed to SNF HAI performance as the lack of information related to the specific infection will not provide actionable information to the SNF. The measure should only include known conditions with known incubation periods and known prevention and treatment approaches. Given the almost complete absence of these conditions in historical

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				hospital claims, we do not believe that removal will reduce the stability of the draft measure **Denominator Statement and Details:** If the proposed draft SNF HAI measure is to remain a Medicare FFS-only measure, then AHCA members agree with the proposal to include all Medicare FFS stays except for stays that meet specific clearly defined exclusion criteria. ***Eligible Stays (Unadjusted Denominator):*** In general, AHCA members support the proposed unadjusted denominator parameters. Specific AHCA comments for proposed Medicare FFS stay exclusions are as follows: 1. Resident is less than 18 years old. AHCA members support the exception rationale as proposed. 2. The SNF length of stay was shorter than four days. AHCA members support the exclusion of SNF short stays (1-3 days) from the denominator population as there is low likelihood of SNF acquired HAIs demonstrating signs or symptoms during this time frame due to incubation windows. 3. Residents who were not continuously enrolled in Part A FFS Medicare during the SNF stay, 12 months prior to the measure period, and 3 days after the end of SNF stay. Given the current challenges accessing meaningful MA enrollee information necessary for adequate risk-adjustment, AHCA members support the exception rationale as proposed. 4. Residents who did not have a short-term acute care hospital stay within 30 days prior to the SNF admission date. The short-term stay must have positive payment and positive length of stay. AHCA members support the exception rationale as proposed.

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				5. Residents who were transferred to a federal hospital from the SNF. AHCA members support the exception rationale as proposed. 6. Residents who received care from a provider located outside of the United States, Puerto Rico, or a U.S. territory. AHCA members support the exception rationale as proposed. 7. SNF stays in which data were missing or problematic on any variable used in the measure construction or risk adjustment. This also includes stays where Medicare did not pay for the stay. AHCA members support the exception rationale as proposed, particularly regarding late or missing hospital claim information beyond the SNFs control. ***Adjusted Denominator:*** CMS and Acumen, LLC. indicate that the proposed 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. AHCA subject matter expert members found that the draft measures document did not contain an adequate explanation or details of this process to be able to offer constructive comment on how the "expected number" is determined for the denominator population. **Statistical Risk Model and Variables**

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				CMS and Acumen, LLC. indicate that the statistical risk model is a hierarchical logistic regression model, which predicts the probability of a HAI that is acquired during SNF care and results in hospitalization. Risk adjusters are predictor variables in the model. Resident characteristics related to each stay and a marker for the specific SNF will be included in the equation. The equation will be hierarchical in that both individual resident characteristics, as well as clustering of residents into SNFs, will be accounted for. Proposed risk adjustment variables described in the draft specifications include: • Age/sex categories: • Original reason for Medicare entitlement (age and disability/ESRD): • Surgery category (if present) on prior short-term claim (e.g., cardiothoracic, orthopedic), grouped using the Clinical Classification Software (CCS) for ICD-10 procedures developed by the Agency for Healthcare Research and Quality (AHRQ) • Receiving dialysis but not ESRD patients (defined as beneficiaries who receive ESRD Medicare benefits): • Principal diagnosis on prior short-term claim, grouped clinically using the CCS for ICD10 diagnoses developed by AHRQ • Comorbidities from secondary diagnoses on the prior short-term claim and diagnoses from earlier short-term stays up to one year before SNF admission (these are clustered using the Hierarchical Condition Categories [HCC] software version 22 groups used by CMS) • Length of stay in the prior short-term hospital stay (categorical to account for nonlinearity): • Prior acute ICU/CCU utilization in the prior short-term hospital stay.

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				• Count of prior short-term discharges within a one-year lookback from the SNF admission date, excluding the most proximal hospitalization claim prior to the SNF admission. AHCA members generally support the proposed risk adjustors but believe the list is incomplete. We also recommend that CMS and Acumen, LLC. consider adding the following proposed risk adjustment variables: • Long-term care facility stays prior to the initial hospital admission. Rationale: Individuals that have had health and mobility impairments significant enough to require 24/7 nursing facility level of care prior to the initial hospital stay are at a higher risk for contracting infections than hospital admissions arising from the community, and would provide a more precise reflection of prior health risk than just counts of prior short-term discharges listed in the proposed variables. • Community infection rates for specific infection types. Rationale: It is well-established, as noted in the 2019 TEP summary report presented with this draft measure, that for certain infections, i.e. particularly communicable airborne pathogens such COVID-19, community behavior and infection rate outside the SNF can and does impact SNF infection rates in those locations. We believe that a risk-adjustor should be added to account for community infection rates for specific ICD-10 codes to reflect the higher risk SNFs in infected communities face. We believe that the TEP may not have thoroughly considered adding this as a risk-adjustment approach as they met in early 2019 – prior to the lessons that have been learned since the onset of the COVID-19 pandemic in the United States in early 2020. We believe this is a rational request as reflected in a recent announcement of the CMS efforts at offering a form of Value Based Payment incentive to SNF providers that best

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				prevent the spread of COVID-19 in their centers. Specifically, the Agency includes the following risk adjustment factor for infection control performance that considers community rates of infection. *Performance measurements for each facility will be evaluated based on the population-wide rate of COVID-19 infection in the geographic area in which a facility is located. The goal is to appropriately evaluate facility performance by measuring the baseline level of infection in the community in which a facility is located.*[11] • Patient cognitive impairment. Rationale: It is unclear to our AHCA member subject matter experts why patient cognitive impairment is not a risk-adjustor for the draft SNF HAI measure because it is a well-known and evidence-based factor. Page 2 of the draft specifications document even states "*Addressing HAIs in SNFs is particularly important because several factors place SNF residents at high risk for infection, including increased age, **cognitive** [emphasis added] and functional decline, use of indwelling devices, frequent care transitions, and close contact with other residents and health care workers."* The current COVID-19 pandemic has confirmed how hard it is to contain infections with patients with cognitive impairments. • The infection-related performance of the discharging hospital. Rationale: As discussed above, to be a meaningful measure that adequately reflects the SNFs infection control performance, the false inclusion of hospital acquired HAIs should be minimized or mitigated. Like the increased risk associated with high community rates of infection, there is higher risk when accepting admissions form a hospital that has substandard infection control performance as compared to hospitals with standard or above standard infection control performance. • Patients who have had several infections in the past. Rationale: Such patients may be at higher risk of ongoing infections (e.g.

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				patient with multiple pneumonias may have inherent immunocompromise that may cause repetitive infections). The risk adjustment should account for previous infection incidence. • Patients with immunocompromising conditions and medications. Rationale: Immunocompromising conditions including but not limited to cancer, chronic inflammatory conditions, and medications that may alter immunity, place certain residents at higher risk of infections as compared to others, rendering a need for adjusting for these factors. • Healthcare disparities. Rationale: While it appears that the TEP panel, convened in May 2019 considered and agreed not to include social factors as risk adjustors but instead study their impact, our AHCA subject matter experts are well-aware that well delineated healthcare outcome disparities have been previously documented among patients and SNFs in the socio-demographically and socioeconomically disadvantaged categories. We are not proposing to create a separate performance threshold (which could perversely incentivize lower quality of care) but are suggesting that the measure developers empirically explore social risk adjustment of this measure, otherwise the measure could have the unintended effect of further entrenching disparities in access and outcomes. **Example Member Subject Matter Expert Responses to Specific AHCA/NCAL Questions Related to the Draft SNF HAI Measure Specifications** ***1. What are your impressions/thoughts on the risk adjustment variables and the approach for risk adjustment?*** AHCA subject matter experts generally agree that the draft SNF HAI measure risk adjustment variables and approach to risk adjustment are difficult to comment on due to incomplete

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				descriptions of the variables and process including the absence of any analytic information (i.e. specific numerator and denominator data) that was discussed in the July 2019 TEP summary report, but not presented for public evaluation. Below are example member statements: • *Adequate risk adjustment is going to be the key for this measure to be fair. (see page 10 above for the AHCA/NCAL subject matter expert developed list of proposed additional risk adjustors that should be added)* • *The exceptions do appear to be thorough to identify factors that do influence HAI's, but I do think the age of the population exclusion should be greater than 18 years old. The age should start with 35 years old range to encompass age range for population.* • *The risk adjustment is not clearly defined, states still under testing. These should have been tested and determined prior to moving to comment period and pre-rule making. To be completely transparent I am lost in the statistical analysis of the risk adjustment. Concern that the preliminary study done was with a very limited sample. If I recall correctly it was 300 or 600 records were used, this is not representative to base determination of quality in HAI prevention upon. In addition; the lack of baseline data to determine the prevalence of HAI post-acute, CMS is determining quality of HAI prevention without knowledge of current HAI's in skilled nursing facilities.* ***2. Do you think this measure is important?*** AHCA subject matter experts agree that a SNF HAI measure is important. Below are example member statements:

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				• *Yes, especially considering all we have seen and dealt with through the pandemic, but I think there needs to be additional and more recent evidenced-based study around this measure looking at both acute and post-acute care. There needs to be a broader look into what occurred with the resident during the Acute stay.* • *Yes, this measure supports a quality of care healthcare delivery, mitigation of complications leading to extended lengths of stay and mitigation of healthcare costs of a preventable medical condition.* • *Prevention of HAI's is important, but this measure is not an accurate measurement of SNF's infection prevention. As mentioned previously the measure is determining quality without knowledge of current/actual HAI's.* ***3. Do you think this measure is feasible as currently defined?*** AHCA subject matter responses were mixed but the consensus was that the currently defined draft HAI measure requires more refinement. Below are example member statements: • *I do believe that there are infections that could have been mitigated by the SNF with earlier detection and identification of precipitating factors. This review will have us looking at our Antibiotic Stewardship Programs as well as long term infections.*

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				• *CMS states that claims data is accurate and reliable since they are used for payment and subject to audit. If inaccuracies are identified in acute care hospital claims, will there be a risk adjustment for these inaccuracies?* 4. ***Do you think this measure is easy to use/any other comments on usability?*** AHCA subject matter responses suggest that there is insufficient detail provided to date to provide a comprehensive response. They appreciated the opportunity to review the Confidential Dry Run Reports for the SNF HAI measure for the FY 2018 and FY 2019 performance years that can be downloaded from their Certification and Survey Provider Enhanced Reports (CASPER) provider shared folders, but the lack of patient level data significantly reduced the usability and usefulness of the reports for quality improvement activities. Members uniformly believe that timely availability of patient specific data reports (i.e. quarterly) will be essential for the usefulness of the measure in informing providers where specific quality areas need to be addressed. There is some concern that the delayed access to hospital data (that may not be consistent with SNF infection-related data) could create more challenges rather than simplifying efforts at improving SNF infection control processes. Below are example member statements: • *The report/measure as is on the Casper currently is not easy to use as the facility is not able to drill down to see what/or who was captured in the reporting to validate for accuracy.* • *The exceptions make it easy for infection control personnel to complete surveillance and target residents that need a focus.* • *No, it is dependent on the diagnosis of medical practitioners that are not under the influence of the skilled provider. No*

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				diagnostic criteria have been established for the inpatient diagnosis. Anecdotally skilled providers see significant numbers of asymptomatic bacteriuria treated during inpatient stays. Studies have shown the inaccuracy of utilizing claims in determining multiple measures and health risks. *As with other quality measures facilities will need to review each resident triggered, providers should be reviewing each rehospitalization determining if avoidable or not and utilizing that analysis for improvement in systems, clinical knowledge and skills, communication systems, and medical provider services. Quality improvement could be prompted with investigation and analysis of the facility records/practices and hospital records. A small study reviewing the inpatient discharge records provided to skilled providers revealed only 45% received diagnostic records and antibiotic history, while this measure excludes pre-existing infections this small study showed deficits in transitions of care.* ***5.* What do you think of the impact of this measure? Any unintended consequences of using this measure?** • *I do believe that it can improve education, surveillance and management of HAI's with a focus knowing the numbers are being tracked and used with Star rating and payment. I think there may be some centers that admit residents as a niche in their community that could be penalized for accepting high risk admissions.*

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				• *Unintended consequences include;* o *Increase in cultures obtained during first four days of admission* o *Facilities may elect to do screening cultures to identify presence of organisms on admission* o *Delay or reluctance for hospital transfers* o *Potential deterioration of hospital relationships if inaccuracies of diagnosis* o *Admission denial decisions made based on risk of rehospitalization, diagnosis and conditions that are increased risk of infection* o *Public admission decision making* ***6.*** **What additional guidance should be required for implementation in the SNF QRP?** • *Accuracy of diagnosis of infections in emergency rooms and hospitals is an issue. For example, there is significant literature that hospitals over-diagnose patients with asymptomatic bacteriuria as "UTI" and "urosepsis". There should be a way to use McGeer's or similar criteria before these readmitted patients are labeled with HAI attributed to SNFs.* • *There needs to be more work from CMS in collaboration with AMDA and other Physician boards around McGeers criteria and antibiotic stewardship with both SNF and Acute Care hospitals and accountability there as well.*

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				• *CMS stated in the TEP and imply in the Usability and Use that skilled providers will/may lead to shorter stays and selective enroll residents. One TEP panelist stated that skilled providers "game the system", submit inaccurate claims, significant errors in MDS's, and cannot be trusted to self-report. As a result of these opinions, quality in prevention of HAI's will be determined by providers outside of the SNF scope of control and influence.* [1] https://www.ahcancal.org/Quality/Quality-Initiative/Pages/default.aspx [2] https://educate.ahcancal.org/products/infection-preventionist-specialized-training-ipco-version-2 [3] https://www.ahcancal.org/Survey-Regulatory-Legal/Emergency-Preparedness/pages/coronavirus.aspx [4] https://www.cms.gov/files/document/development-skilled-nursing-facility-snf-healthcare-associated-infections-hais-requiring.pdf [5] https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/SNF-HAI-Final-TEP-Report-7-15-19_508C.pdf [6] MedPAC, Report to the Congress, March 2020, Chapter 8, Skilled Nursing Facility Services. http://www.medpac.gov/docs/default-source/reports/mar20_medpac_ch8_sec.pdf?sfvrsn=0 [7] 2020 Medicare Trustees Report. https://www.cms.gov/files/document/2020-medicare-trustees-report.pdf

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				[8] https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/SNFPPS/therapyresearch. [9] Figure excerpt from Barnett,ML; Hu, L; and Martin, T. Mortality, admissions, and patient census at SNFs in 3 US cities during the COVID-19 pandemic. JAMA. 2020;324(5):507-509. doi:10.1001/jama.2020.11642 https://jamanetwork.com/journals/jama/fullarticle/2767750 [10] Centers for Disease Control. *Interim Clinical Guidance for Management of Patients with Confirmed Coronavirus Disease (COVID-19)*. https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidancemanagement-patients.html. Accessed October 9, 2020. [11] Department of Health and Human Services, CARES Act Provider Relief Fund: FAQs: Nursing Home Infection Control Distribution. https://www.hhs.gov/coronavirus/cares-act-provider-relief-fund/faqs/targeteddistribution/index.html#nursing-home Accessed October 9, 2020.
13	10/14/2020	Roxanne Tena-Nelson Interim President/Senior Advisor and Special Counsel	Continuing Care Leadership Coalition (CCLC)	**October 14, 2020** Acumen, LLC 500 Airport Blvd., Suite 100 Burlingame, CA 94010 *Electronic Submission Via:* QM-Public-Comment@acumenllc.com Subject: Contract number 75FCMC18D0015. Development of the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program.

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				To Whom It May Concern: The Continuing Care Leadership Coalition (CCLC) represents the not-for-profit and public long term care provider community in the New York metropolitan area. The members of CCLC provide services across the continuum of long term care (LTC) to older and disabled individuals. CCLC's members are leaders in the delivery of skilled nursing care, home care, adult day health care, respite and hospice care, rehabilitation and sub-acute care, senior housing and assisted living, and continuing care services to special populations. CCLC's members have also had a significant impact on the development of innovative solutions to long term care financing and service delivery in the United States, including having played pioneering roles in the development of managed long term care programs in New York and Medicare managed care and Program for All-Inclusive Care for the Elderly (PACE) programs for dual eligibles at the national level. CCLC supports the use of quality measures for quality assurance and performance improvement activities in skilled nursing facilities (SNFs). On behalf of the long term care providers in the CCLC membership, I appreciate this opportunity to comment on the Development of the Skilled Nursing Facility Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program. **Measure Description**

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				CCLC appreciates CMS's efforts to update the quality measures for public reporting to focus on improving outcomes for SNF residents, which is consistent with CCLC members' mission-driven commitment to high quality care. CCLC strongly supports CMS's intent to develop and test specific risk-adjustment methodologies to account for distinct facility characteristics. However, CCLC recommends further consideration for variables that are sensitive to the diverse array of special population providers that care for people with -- for example -- HIV/AIDS, psychiatric diagnoses, traumatic brain injury, Huntington's Disease, and those who are ventilator-dependent. **Measurement Period** CMS proposes that this period begin on day four after SNF admission through day three after SNF discharge. CCLC recommends that CMS give close attention to unintended consequences from this proposed measurement window, including early or avoided transfers to the hospital that could disrupt necessary access to appropriate level of care. Furthermore, careful review of relevant attribution approaches should be completed to ensure that this window is reliable in assigning only those HAIs for which SNFs are primarily responsible. **HAI Criteria** The draft HAI conceptual criteria comprise: 1) infections that are likely to be acquired during SNF care and severe enough to require hospitalization, and 2) infections related to invasive medical devices. CCLC members strongly support the inclusion of only "severe" cases, as they constitute reasonable triggers for hospitalization.

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				Concerning performance improvement, these cases alone make up hundreds of diagnosis codes, and pose challenges in tracking and monitoring. CCLC agrees with CMS's plan to factor in pre-existing conditions and to use the Centers for Disease Control and Prevention's (CDC's) National Healthcare Safety Network (NHSN) Repeat Infection Timeframe (RIT) of 14 days (with modified RIT day one specification) for these conditions to rule out hospital-acquired infections. **Exclusions** CCLC concurs with the following list of suggested exclusions for this measure: individuals under 18 years old because they present with characteristics and care issues that may not be reasonably compared with the geriatric population, as well as those that would pose the lack or absence of substantiated data. Similarly, CCLC supports the exclusion of emergency department visits and observation stays due to the short turnaround time that inhibits the acquisition of laboratory results for proper diagnosis of HAI. **Data Source and Collection** CCLC firmly favors CMS's intent to prioritize patient care over paperwork and is pleased with this proposed measure's ability to leverage available data through inpatient hospital claims to inform CMS. At the same time, CCLC advocates for provider access to real-time or closer to real-time information that could help impact

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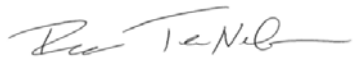
				performance improvement. Accordingly, CCLC approves of the technical expert panel's (TEP's) recommendation that CMS furnish providers with quarterly claims data through the Certification and Survey Provider Enhanced Reporting (CASPER) system to make the measure more actionable. CCLC also supports the thoughtful consideration of social determinants of health and the specific circumstances of individuals dually eligible for Medicare and Medicaid in the context of data sourcing and collection processes. **Conclusion** CCLC and its members are concerned about the lack of empirical evidence that demonstrates the relationship between distinct interventions and HAI rates in SNFs. In connection with this, CCLC resolutely urges CMS to proceed with prudent investigation of this measure's specifications and potential impact to resident care. Moreover, CCLC emphasizes the need for CMS to address barriers such as the lack of standardization of infection diagnoses and management in SNFs and across settings, and the deficiencies in provider training as part of its plan to effectively implement this measure. On behalf of CCLC and its members, I want to reiterate my appreciation for the opportunity to comment on this proposed measure. Should you need further information, or if you have questions about these comments, please contact me at CCLC. Sincerely, 

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				Roxanne Tena-Nelson Interim President/Senior Advisor and Special Counsel Continuing Care Leadership Coalition 555 West 57th Street, Suite 1500 New York, NY 10019 (212) 506-5400 Tena-nelson@cclcny.org
14	10/14/2020			October 14, 2020 The Honorable Seema Verma Administrator Centers for Medicare and Medicaid Services Department of Health and Human Services P.O. Box 8011 Baltimore, MD 21244–1850 Submitted via QM-Public-Comment@acumenllc.com RE: Development of the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program (SNF QRP) Dear Ms. Verma, The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to submit comments on the proposed healthcare-associated infections (HAIs) quality measure for the skilled nursing facility (SNF) Quality Reporting Program (QRP). 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

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				preventing and controlling morbidity, mortality and the cost of care linked to healthcare-associated infections (HAIs) and antibiotic resistance. After careful review of the proposal outlining this SNF QRP measure, SHEA does not support it as drafted and does not recommend its adoption as presented. While SHEA supports efforts to improve the quality of care delivered in the long-term care setting through QRP, this 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 7. Incubation period for infections The contractor proposes identification of HAIs based on ICD-10 codes upon admission to the hospital. While it may seem that using ICD-10 codes in the 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. The contractor should consider the revised McGeer criteria[1], which assess infections in long-term care (LTC) settings. The contractor should also carefully consider using alternate thoughtfully developed definitions already used to assess infections in LTC settings which are grounded in evidence, agreed upon by experts, and already used in real-world settings.

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				In addition to general concerns about the accuracy of using ICD-10 codes for surveillance, the proposed approach relies on an assumption that hospitals would correctly and accurately classify symptoms and diagnoses upon discharge from their facility 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 of these 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. 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 codes inclusions 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. • Cellulitis *Urinary tract infection, site not specified.* In the case of urinary tract infections (UTI), many patients are admitted with UTI due to

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				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 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. 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). Thank you in advance for your consideration of our comments. Please do not hesitate to reach out with questions to Lynne Batshon,

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				Director of Policy and Practice, at (703) 684-0761 or lbatshon@shea-online.org. Sincerely,  Mary Hayden, MD, FIDSA, FSHEA President-Elect SHEA [1] Stone ND, Ashraf MS, Calder J, et al. Surveillance definitions of infections in long-term care facilities: revisiting the McGeer criteria. Infect Control Hosp Epidemiol. 2012;33(10):965-977. doi:10.1086/667743
15	10/14/2020	Connie Steed, MSN, RN, CIC, FAPIC 2020 APIC President	Association for Professionals in Infection Control and Epidemiology (APIC)	October 14, 2020 Ms. Seema Verma Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services Room 445–G Hubert H. Humphrey Building 200 Independence Avenue, S.W. Washington, DC 20201 **RE: Draft Measure Specifications: Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalizations for the Skilled Nursing Facility Quality Reporting Program** Dear Ms. Verma:

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				The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide input to the "Draft Measure Specifications: Skilled Nursing Facility Healthcare-Associated Infections (HAIs) Requiring Hospitalizations for the Skilled Nursing Facility Quality Reporting Program". APIC is a nonprofit, multidisciplinary organization representing 16,000 infection preventionists whose mission is to create a safer world through prevention of infection. We are pleased that CMS continues to demonstrate its commitment to improving the quality of patient/resident care across the healthcare continuum. We have seen the positive impact required reporting has in the prevention of HAIs in acute care facilities and support continued expansion of these best practices across the continuum.[1] APIC supports including this HAI reporting measure in the Skilled Nursing Facility Quality Reporting Program in order to acquire actionable data that will aid in implementation of evidence-based infection prevention strategies to improve the quality of care. CMS proposes to utilize administrative claims-based data to identify HAIs related to care in skilled nursing facilities (SNFs). APIC notes that exclusive use of administrative data is not a precise measure for identifying HAIs. We recommend use of standardized definitions and risk-adjusted data to provide actionable information for clinicians and patients/residents alike when determining infection status.[2] APIC supports the use of administrative data as one component for this measure so we can begin the measurement process that spurs improvement. We understand data was provided that demonstrated alignment of administrative data between SNFs and acute care facilities, and we do agree with the technical expert panel that the real-life experience may differ from the study findings. However, based on experience with Hospital Acquired Condition (HAC)/Present on Admission Indicators which, for the first time, tied

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				Medicare reimbursement to quality of care, the use of administrative data can lead to examination of current processes, collaboration, and improvement within and between facilities, leading to refinement toward a more precise measure. APIC encourages ongoing evaluation for the effectiveness of this new measure approach in conjunction with SNF and Infection Prevention and Control stakeholders. APIC agrees with the inclusions and exclusions of the HAI conditions listed in Appendix A Table 1. We enthusiastically support the alignment with the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) infection time window and utilization of a standardized risk ratio to compare standardized populations. APIC also supports the claims-based quality measures proposed for the risk adjustment model. While we commend CMS' commitment to incorporate these recommendations into the SNF HAI specifications to further align across measures, we express concern that the measure is not endorsed by a consensus organization such as the National Quality Forum (NQF). We advocate for use of NQF-endorsed measures as the NQF process includes a robust measure review with routine measure updates and maintenance as performance and evidenced-based research changes. APIC appreciates the opportunity to provide our perspective on the measure specifications and we look forward to continuing to work with CMS to ensure patient/resident safety through the prevention and control of infections. Sincerely,

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				 Connie Steed, MSN, RN, CIC, FAPIC 2020 APIC President _____ [1] Centers for Disease Control and Prevention: 2018 National and State Healthcare-Associated Infections Progress Report, November 1, 2019. Available at https://www.cdc.gov/hai/data/portal/progress-report.html. Accessed 10/13/2020. [2]APIC Position Paper: The Use of Administrative (Coding/Billing) Data for Identification of Healthcare-Associated Infection in US Hospitals, October 12, 2010. Available at http://apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/ID_of_HAIs_US_Hospitals_1010.pdf. Accessed 10/13/2020.
16	10/14/2020	Amir Hajimomenian, MD, CMD, President	Mid-Atlantic Long Term Care	To Whom it May Concern: As clinicians specializing in the practice of medicine in the long-term care setting, many of us have often been frustrated by our patients being hospitalized with clinically unwarranted diagnoses of infection. CMS has promoted appropriate antibiotic stewardship programs, but it's evident that such principles are not effectively implemented in many acute care facilities. Antibiotic stewardship promotes application of standard diagnostic criteria, yet far too often an abnormal urinalysis and/or culture alone begets diagnosis and treatment of urinary tract infection in the acute setting. Analogous issues apply to pneumonia. Furthermore, a patient that is dehydrated can readily meet criteria for sepsis (e.g., tachycardia, hypotension). Similarly, there are many instances where patient has elevated lactic acid and increase heart rate or respiratory rate clearly attributable to other causes (e.g., COPD exacerbation, seizure any underlying

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				disease with hypoxia). Thus, while it is very important to identify sepsis early to reduce mortality, current criteria are over diagnosing sepsis. Given the many instances of patients meeting criteria for sepsis that do not have infection at all, simply removing unspecified sepsis from the list of diagnoses triggering the proposed measure would be a step in the right direction. The issue would likely not exist except for the fact that financial incentives promote knowingly false coding of infectious illness. Some of us have witnessed first-hand hospital clinicians being written up if for not coding sepsis and using a fluid bolus and triple antibiotic, despite their clinical judgement. Many of us have had patients sent to the ER for treatment of a simple mechanical injury surprisingly admitted for urosepsis +/- pneumonia, especially if beds are available and the patient hasn't been hospitalized recently enough to count against the hospital's readmission measures. The antibiotic stewardship agenda is valuable and should be emphasized more in the acute care setting. Clinical standards for diagnosis and coding of an infection (e.g., McGreer criteria for UTI) should be promoted in all settings. Financial incentives and/or enforcement actions should be adapted at least to the extent that they do not run counter to these concepts. Already, funding and other policy decisions have been made based on claims data that is flawed due to the bias of financial incentives. The proposed Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations measure as it stands would be another inherently flawed manifestation of this. It may be a better measure of the financial acumen of the hospital(s) around a nursing facility than the quality of the infection prevention and control practices of the facility itself. The measure should not be implemented until these other systematic issues are substantially corrected.

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				On Behalf of Mid-Atlantic Long Term Care,  Amir Hajimom enian, MD, CMD President
17	10/14/2020	Blair Childs Senior Vice President, Public Affairs	Premier Inc.	October 14, 2020 The Honorable Seema Verma, MPH Administrator Centers for Medicare & Medicaid Services Department of Health and Human Services P.O. Box 8013 7500 Security Boulevard Baltimore, MD, 21244-1850 Submitted electronically to: SNFQualityQuestions@cms.hhs.gov ***Re: Measure specifications for the Skilled Nursing Facility (SNF) Healthcare Associated Infections (HAIs) Requiring Hospitalization.*** Dear Administrator Verma: On behalf of the Premier healthcare alliance uniting more than 4,100 U.S. hospitals and health systems and approximately 200,000 other providers and organizations, we appreciate the opportunity to submit comments on the measure specifications for the Skilled Nursing Facility (SNF) Healthcare Associated Infections (HAIs) Requiring Hospitalization. With integrated data and analytics, collaboratives,

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				supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Through its Alternate Site Programs division, Premier serves more than 28,000 nursing homes around the country. In our comments, Premier urges CMS to: • Explore policy options to incentivize SNFs to adopt clinical surveillance technology to reduce and prevent HAIs; • Fully test SNFs claims data at different starting points for the claims window to ensure that the fourth day is appropriate; • Focus on actionable outcomes rather than one broad claims-based measure; and • Not implement the HAI measure until after the COVID-19 public health emergency has expired. CLINICAL SURVEILLANCE TECHNOLOGY AS A SOLUTION FOR SNFs Premier recognizes the critical need for preventing and reducing HAIs across the healthcare system and supports CMS efforts to advance measures to assess HAIs in SNFs. One step further, we believe CMS should pursue mechanisms that will reduce HAIs in the first place and lead to better quality outcomes. In the acute care setting, Premier is an established leader in implementing clinical surveillance systems to help translate data into action to improve patient outcomes. Premier continues to focus on clinical analytics technologies that detect patient care issues with the surveillance, interventions and reporting capabilities that are needed to support antimicrobial stewardship programs that reduce HAIs. More than

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				1,000 facilities use Premier's clinical surveillance technology, powered by TheraDoc®, that delivers a comprehensive, easy-to-use solution that helps clinicians individualize antibiotic therapy. The clinical surveillance system utilizes data from electronic health records (EHRs), helping clinicians and pharmacists identify overuse of antibiotics and drug-bug mismatches, reduce time-to-appropriate therapy and enhance therapy for difficult-to-treat pathogens. Based on the success in acute care settings, we believe SNFs would benefit by implementing clinical surveillance systems that would allow them to: • Discontinue medications where there was a drug-bug mismatch or where unnecessary; • Prevent adverse drug events; • Switch from intravenous medications to less expensive oral formulas; • Eliminate redundant antimicrobials; • Switch patients to narrower and less expense antimicrobials; • Shorten the duration of drug therapy to align with recommended guidelines; and • Restrict the use of certain drugs without approval of an infectious disease specialist. Unfortunately, clinical analytics technologies are currently not widely used in SNFs. SNFs should have the same access to tools that will help them combat infection spread during any future outbreaks of COVID-19 and during their day-to-day operations, but unfortunately funding remains a significant barrier. ***Therefore, in addition to measure development, Premier urges CMS to explore policy options to incentivize SNFs to adopt clinical surveillance technology to reduce and prevent HAIs.*** MEASURE SPECIFICATION FOR SNF HAIs

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				Regarding the measure specifications for the SNF HAIs requiring hospitalization, Premier has three main concerns regarding the measure: • The Medicare claims window that begins on the fourth day of the SNF stay and within the third day after a nursing home discharge may not accurately capture HAIs that originate in the SNF. • Relying on a claims-based, composite measure may not lead to meaningful process improvements. • Implementing the measure during the COVID-19 public health emergency (PHE) may inaccurately capture the quality of care in a SNF. Our concern regarding the claims window starting on the fourth day of the SNF stay is that this may be too soon in the SNF stay to eliminate those instances where the infection was present in the patient before the SNF admission. The proposed timeframe for measurement may hold a SNF accountable for an infection that was not acquired at the facility. ***Premier urges CMS to fully test SNFs claims data at different starting points for the claims window to ensure that the fourth day is appropriate***. CMS should thoroughly analyze and compare different window starting points to confirm with data the appropriate time duration for the claims window after SNF admission. Additionally, we are concerned that the claims-based measure may not be actionable for SNFs from an improvement perspective. For instance, it may be more meaningful for the measure to be segmented by infection type, such as catheter-associated urinary tract infections (CAUTIs), clostridioides difficile infection CDIs and others, so the facilities can make specific improvements. ***Premier urges CMS to implement meaningful metrics and tools for SNFs to assess their***

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				performance rather than base performance on one broad claims measure. Further, Premier shares the concerns of SNFs that implementing the HAI measure during the COVID-19 PHE will create significant problems for accurate measurement. Given the tremendous pressure placed on SNFs during the PHE and the fact that each SNF continues to be disrupted by COVID-19 in different ways, we believe CMS should continue to evaluate the stability of the measure but not implement it until at least after the PHE has expired. ***Premier urges CMS not to implement the HAI measure until after the PHE has expired***. **Conclusion** In closing, the Premier healthcare alliance appreciates the opportunity to submit comments on the measure specifications for the SNF HAIs requiring hospitalization. Premier looks forward to working with CMS and other stakeholders to develop reforms that meet the agency's goals and are appropriate for beneficiaries and providers. If you have any questions regarding our comments or need more information, please contact Shara Siegel, Director of Government Affairs at shara_siegel@premierinc.com or 212-901-1264. Sincerely,  Blair Childs Senior Vice President, Public Affairs Premier Inc.

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18	10/14/2020	Debra Wertzberger	Sante Operations	On Behalf of our Sante Operations located in Arizona and Washington State we respectfully submit for immediate consideration to the proposed changes related to QM's and HAI's the following. One qualifying statement we ask you to keep in mind is not unlike others who are licensed Medicare SNF's our facilities are operating at a sub-acute, short stay rehab and Skilled Nursing level of care. We are not LTC and we are not traditional clinical model of SNF. Thank you in advance for your consideration to our comments. • HAIs need to have a clearly defined timeline of what is determined to be acquired at the SNF. Example: day four after SNF admission-not be considered a SNF HAI or 3 days after SNF discharge (already exists) but is not always applicable. • Any preexisting conditions must not be considered in this number. Example: C-diff infection after receiving pre-op IV ABT for surgery - or any other antibiotic that predisposes the patient to C Diff infection. • HD catheter/port related infections that are not accessed at our facility should not be considered an SNF HAI. • Patients who are high risk and have had multiple hospitalizations and SNF stays within a certain period should not be counted as a SNF HAI. • Agree with all of the risk adjustments on page 9 • PG 10 – Step 2: 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

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				the prior proximal hospitalization must be a diagnosis that is related to the HAI recorded in the re-hospitalization. • The hospital does not always accurately report or record infections. So, if it is not accurately reported on the proximal hospitalization claim prior to SNF admission then it may be considered SNF Acquired. • p.12 SNFs are required to report HAIs requiring hospitalizations- Arizona does not share one medical record to know these things. We may send patients to the ER and never hear a word again, patients can block access to HIE, how would we know in those instances if it was infection? • Dx on pgs 15-67 need to be evaluated if any can be brought in from community visitors such as scabies, upper and lower respiratory infections ie pneumonia, flu, strep throat, pharyngitis, tracheitis, whooping cough, GI infections, conjunctivitis- if these infections are not present in house. How do we determine they are HAI if there could potentially be another source. • Review conditions that are local skin infections cause by underlying disease such as gas gangrene, septic arterial embolism, septic pulmonary embolism, endocarditis, abscess of lung, • COVID- 19 is a worldwide pandemic currently, how can we be solely responsible for the transmission of this organism and penalized for it? • Must take into consideration that patients go to appointments where they could be exposed or compromised, such as surgeon's offices, dialysis, hospital outpatient services, transport? How is it determined to put the onus on a SNF when that is not the only place they are and their staff are not only people they are with for their stay.

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				• What about providers going from facility to facility - SNF to SNF, hospital to SNF who may not be at the level of standards at using PPE and washing hands and we will be responsible for the HAI? • In the hospital it is easy to track because the patient never leaves. In a SNF the patient is absolutely more mobile as they prepare to safely transition home. • Consideration to a stipulation that says -if the patient has not left the facility AT ALL. Then it may be an HAI. • There are too many extenuating circumstances and factors for SNF patients- strictly rehab to be able to say the infection is HAI. Absolute factors must be determined in order to prove it was acquired at the SNF. • Easier for LTC to determine because the residents live there and so the onus would be on facility but not for rehab skilled nursing that focus is on shorter LOS and acute medical. We do see a volume of infections admitted to our facilities and therefore considerations have to be made to ensure "exclusions" in the numerator are factored in for short-stay residents. Likewise, the time-measure of "the time window beginning on day four after SNF admission and within day three after SNF discharge" is too stringent as we know infections have varying incubation periods. We understand the "timing" of the release of this QM, however, we are still in the midst of a pandemic and a virus that we are still trying to fully understand. We do not think it is fair for CMS to expect "SNFs"" to manage effectively when guidance and care/treatment

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				protocols are still evolving. We strongly ask for a "PAUSE" until there's a better understanding of what we are up against. As a final consideration: ER and OBS don't count towards the numerator. Variability occurs inherently with ER Physician and Hospitalist practice patterns that may impact decision to transition to inpatient when acute hospital inpatient stay may not be justified. Obviously this would be challenged on the back end by payors for aberrant hospital stays. • Why this is important: The numerator may become "inflated" by provider practice pattern variability. This is not within the control of the SNF and may skew outcome measures.
19	10/14/2020	Rachel Fleischer Senior Federal Relations Specialist and Kathryn E. Spates, JD, Executive Director, Federal Relations	The Joint Commission	October 14, 2020 Ms. Seema Verma Administrator c/o Acumen Centers for Medicare & Medicaid Services Department of Health and Human Services Hubert H. Humphrey Building 200 Independence Avenue, S.W. Washington, DC 20201 [Re: Project: Development of the Skilled Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program (SNF QRP); Submitted electronically to QM-Public-Comment@acumenllc.com.] Dear Administrator Verma: The Joint Commission appreciates the opportunity to comment on the development of the Skilled

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				Nursing Facility (SNF) Healthcare-Associated Infections (HAIs) Requiring Hospitalizations Measure for the Skilled Nursing Facility Quality Reporting Program. Founded in 1951, The Joint Commission seeks to continuously improve health care for the public in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value. An independent, not-for-profit organization, The Joint Commission accredits and/or certifies more than 22,000 health care organizations and programs in the United States. The Joint Commission evaluates health care organizations across the continuum of care, including most of the nation's hospitals. In addition, Joint Commission programs encompass clinical laboratories, ambulatory care and office-based surgery facilities, behavioral health care, home care, hospice, nursing care centers, and long-term care organizations. Joint Commission accreditation and certification are recognized nationwide as symbols of quality that reflect an organization's commitment to meeting state-of-the-art performance standards. Although accreditation is voluntary, a variety of federal and state government regulatory bodies, including the Centers for Medicare and Medicaid Services (CMS), recognize and rely upon The Joint Commission's decisions and findings for Medicare or licensure purposes. Although the proposed measure may assist SNFs with quality improvement related to HAIs, we have concerns about the use of claims-based measures for accountability purposes (i.e., public reporting and pay-for-performance programs). Studies have shown that claims-based measures often do not capture the outcome of interest accurately and do not adequately adjust for differences in severity of illness (i.e., case mix) across healthcare organizations. For these reasons, most claims based measures do not meet our

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				accountability criteria for outcome measures (Baker and Chassin, Annals of Internal Medicine, 2017). The Joint Commission is pleased to answer any questions you may have regarding our feedback to this measure. If you have any questions, please do not hesitate to contact me or my staff: Rachel Fleischer at 202-783-6655 or rfleischer@jointcommission.org. Sincerely, Kathryn E. Spates, JD Executive Director, Federal Relations
20	10/29/2020	Jennifer Lamprecht, MS, RN, CNL, CPHQ Director of Quality Strategy and Sue Hohenthaner, Lead Infection Prevention Strategist	Sanford Health	October 29, 2020 Center for Clinical Standards and Quality Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, MD 21244 **Re: Draft Measure Specifications:** **Skilled Nursing Facility Healthcare-Associated Infections Requiring Hospitalization for the Skilled Nursing Facility Quality Reporting Program** To Whom It May Concern, Sanford Health is a non-profit integrated health system headquartered in the Dakotas. We are one of the largest health systems in the nation with 44 hospitals, 1,400 physicians, and more than 200 Good Samaritan Society senior care locations in 26 states and nine countries. Sanford Health's 48,000 employees make it the largest employer in the Dakotas.

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				We appreciate the opportunity to comment on the draft specifications for the SNF infections measure. After reviewing the proposed specifications, we have comments as outlined below: 1. Measure Population The patient population included in this measure is somewhat narrow as it only includes SNF residents who had a hospitalization within 30 days prior to the SNF admission. This likely results in a more homogenous group from a data perspective, but does not measure quality of care for many SNF residents. Hospital claims are a good data source for comorbidities used in risk adjustment, but with the one year claims look back, a prior hospitalization should not be required to be included in the measure. Another group of patients that would not be included are those who get an infection at the SNF, but choose not to seek hospital care. These infections may contribute to a mortality and not be counted in this quality measure. 2. Claims Based Infections Using claims based data to identify infections is not as complete and reliable as surveillance. Ten comprehensive academic medical centers from across the country were selected from our benchmarking vendor's database. The number of PSI-7 cases in calendar year 2019 was compared to the number of CLABSIs reported on Data.Medicare.Gov also for 2019. PSI-7 Central venous catheter bloodstream infection is a claims based infection measure and medicare.gov data comes from surveillance data recorded in NHSN. The NHSN reported CLABSI numbers were 2 to 16 times that of the PSI-7 volumes for the same year. Calculating infection rates using claims

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				based data may underestimate the patient harm that is occurring. 3. Repeat Infections The fourteen day timeframe used to identify repeat infections is a new concept. This does not align with surveillance criteria and may be confusing for infection prevention staff, especially if they work with data for other types of healthcare settings like a critical access hospital. We appreciate CMS's consideration of these comments. Sincerely,  Jennifer Lamprecht Director Quality Strategy Sanford Health Sue Hohenthaner Lead Infection Prevention Strategist Sanford Health