October 13, 2020

Lee Fleisher, M.D.
Chief Medical Officer and
Director of Center for Clinical Standards and Quality
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: 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 Even these estimates are uncertain, and many are outdated."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.

CMS itself has found that administrative claims data are not reliable to inform HAI measure performance. For example, in a 2012 reliability analysis, CMS's contractor found that several claims-based hospital-acquired condition (HAI and patient safety indicator) measures had low and very low reliability; a 2012 Medicaid report on state reporting of the central line-associated blood stream infection (CLABSI) measure found that "administrative data (discharge or claims-based) substantially underestimate rates of CLABSI…effectively ruling out the use of administrative data at the current time as a legitimate approach to generating state-level, insurance-specific rates." In regards to ICD-9 (now ICD-10) coding that informs claims, the 2013 National Action Plan to Prevent Health Care-Associated Infections noted "coded diagnosis of UTI, CAUTI, and CDI is neither a sensitive nor a specific indicator of clinical diagnosis." Several other studies show that administrative data is not able to reliably predict outcomes. The literature review conducted by contractor RTI International for the TEP cited additional studies that concluded that administrative data (i.e., claims data) results in under-, over-, and misclassified reporting of health outcomes.

This measure's reliability also is questionable due to upstream data collection issues – namely, in detection of HAIs. As constructed, the measure would include only those SNF patients who go from a SNF to an acute care hospital, and for which *the hospital*

submits a Medicare claim indicating BOTH that the HAI was the principal admitting diagnosis AND had the HAI at the time of admission (i.e., with a present on admission code). At a minimum, this construction is likely to omit some SNF patients who have an HAI simply because the HAI is not either recorded as the principal diagnosis, or present on admission. Nevertheless, the supporting documents for this measure conclude that existing HAI measures "all report on specific types on infections rather than on the overall HAI rate," and thus this measure, a composite of-sorts, would fill a gap. There is a reason that existing HAI measures are specified as such: tests for various infections are different, with different levels of sensitivity and specificity. With such varying inputs, it is difficult to see how a composite measure would provide accurate (and thus actionable) information. In addition, hospital tests of HAIs vary as well; it is possible that certain hospitals will be better able to detect HAIs than others, and thus SNF performance might be a factor of hospital data collection rather than true quality of care.

Overall, the actionability of the measure – that is, whether providers will be able to use information gleaned from this measure to improve quality – is unclear. While there are common-sense practices that lower the likelihood of HAIs in SNFs, most specific clinical interventions are defined for the hospital setting rather than the SNF setting. Without clear clinical evidence of the relationship between the provider's actions in a SNF and the resident's health as a result of his/her stay, the measure may not be able to detect usable information.

In addition, the construction of this measure makes the assumption that the only HAIs that truly "matter" are those resulting in hospitalization. Yet, successful HAI reduction efforts depend on the rapid and timely identification of infections so that their underlying causes – infection control, environmental, physical plant, etc. – can be addressed *before* they result in morbidity or mortality. That is why existing HAI measures use detailed surveillance definitions we describe above, and are collected using actual medical record data. This approach ensures that providers know quickly which patients are infected, and can rapidly take infection control steps to protect other patients and staff from infection. Patients and providers cannot afford to wait two to three years to have incomplete claims-based data inform HAI reduction efforts. And for the reasons we describe below, this claims-based measure is likely to be a poor reflection of providers' actual performance.

Several factors at the patient and provider level influence outcomes, but they are not incorporated into the risk adjustment methodology for this measure. The supporting literature states "Research suggests that infection rates vary by provider characteristics" including staffing levels, staffing type (i.e., RN versus LPN), organizational structure (i.e., national chain versus independent facility), case mix, payer mix, and adoption of infection surveillance and prevention policies. Several other provider characteristics that may affect performance have not yet been

investigated, including size, market (rural/urban or region) and whether the SNF is hospital-based. NHSN also collects information on patient days in admission, teaching status, and where microbial testing is done (in the facility versus a commercial reference lab).

Patient-level characteristics, which are outside of the provider's control, also influence infection rates. Literature shows that social risk factors, including income level and race/ethnicity are associated with varying infection rates due to "more disparities in access to care among patients in the community than in SNFs," suggesting that certain residents are less likely to receive preventive care in the community and are thus at increased risk of infection. A more precisely-constructed HAI measure may not need to account for social risk factors because the surveillance definitions are specific enough to ensure they are truly reflecting those infections acquired in the course of receiving health care. But this measure does not have such definitions, making it vital that the role of social risk factors in performance be assessed and accounted for if appropriate.

Because of the myriad factors affecting outcomes like HAIs, a composite measure such as this one may not provide information that providers can use to address specific risks to their patients. Even if the information gleaned from this measure were reliable, however, additional barriers remain to putting that data to use. While SNFs agree with the need to reduce HAIs, many operate under significant financial strain, and may not have the same depth of resources to apply to quality improvement efforts. We encourage CMS to deploy quality improvement support to help accelerate progress on reducing HAIs in SNFs. This model has worked incredibly well for hospitals, as evidenced by the rapid progress of CMS's Hospital Innovation and Improvement Networks. It is conceivable that smaller SNFs with fewer resources could appear to perform worse than their competitors through no fault of their own (i.e., based on the influence of patient-level factors or differences in hospital surveillance). In the future, this measure might be incorporated into the SNF Value-based Purchasing program, in which the described scenario would result in direct financial harm to already disadvantaged facilities.

In the end, accountability measures like this one are useful only when they can accurately characterize performance. SNFs would welcome a well-designed measure that can help them understand where they are performing well, and where they can improve. However, for the reasons outlined above, we are not confident that this measure delivers on that critically important task. It is also challenging to conceptualize an evaluation of facility performance based on claims filed by a totally different facility; we understand and appreciate that CMS is seeking measures that do not pose undue burden on providers (as claims-based measures require no data submission on the part of providers), but for some topics the burden is worthwhile. **Burden is outweighed by the benefits of truly meaningful measures that**

uncover discrepancies in performance and provide actionable data that will result in better patient outcomes. We suggest CMS scrap this measure and develop one that is timely and actionable.

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