American Hospital Association™
Advancing Health in America

Washington, D.C. Office
800 10th Street, N.W.
Two CityCenter, Suite 400
Washington, DC 20001-4956
(202) 638-1100

June 7, 2021

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Room 445-G
Washington, DC 20201

CMS-1746-P: Medicare Program; Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) for Federal Fiscal Year 2022.

Dear Ms. Brooks-LaSure:

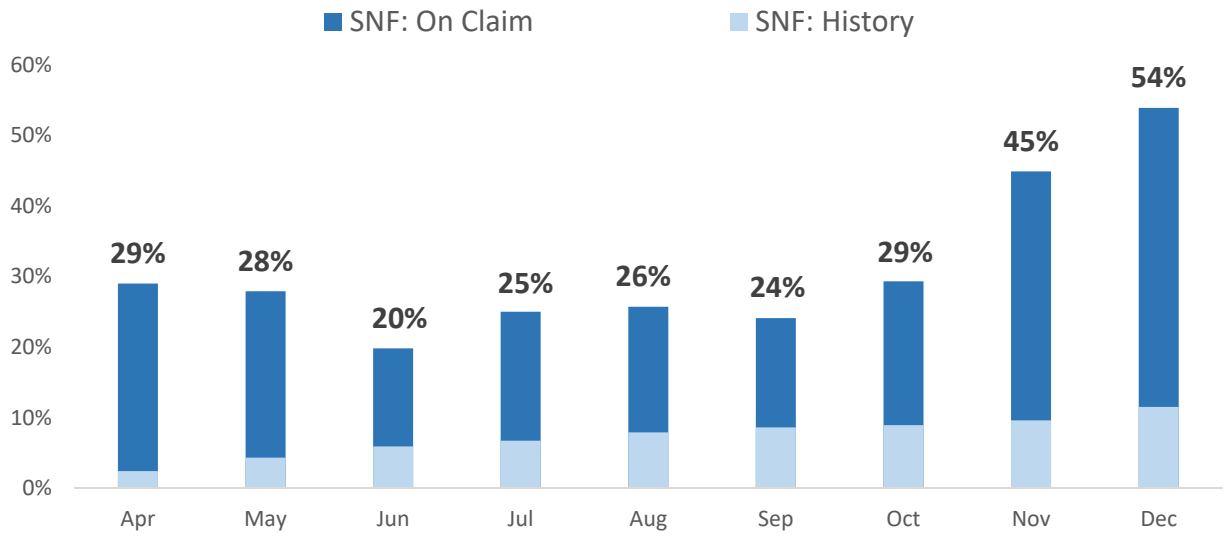
On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 750 hospital-based skilled-nursing facilities (SNFs), and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health 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) fiscal year (FY) 2022 proposed rule on the SNF prospective payment system (PPS). This letter focuses on the payment provisions that would be affected by COVID-19-driven dynamics, as well as several key proposals related to quality reporting, and the agency's requests for information on health equity and digital quality reporting.

In addition to the issues discussed in this letter, the AHA expresses sincere thanks to the agency for the elements in the proposed rule that demonstrate CMS' active support of the field at this critical time. For example, we particularly appreciate the agency's decision to not yet propose an addition to the "parity adjustment" designed to ensure budget neutral implementation of the new case-mix system, known as Patient Driven Payment Model (PDPM), in FY 2020, and to confirm that any future adjustment would be implemented on a prospective basis. These positions give the SNF field the much-needed space to address the devastating effects of the pandemic, including retooling personnel training and clinical protocols, implementing physical plant modifications, and other actions to enhance competencies and secure patient safety.

Hospital-based SNFs and COVID-19
The AHA appreciates CMS' streamlined proposed rule, which allows hospital-based SNFs, their host hospitals, and other local partners to focus on their COVID-19 response. This approach, in combination with the pandemic-related waivers authorized by Congress and CMS are enabling hospital-based SNFs to continue to make a difference in the COVID-19 fight in communities still experiencing surges, as well as effectively care for patients recovering from the virus, who need clinical support to address longer-term virus after effects.

The public health emergency (PHE) flexibilities that CMS implemented during FY 2020, which continue in FY 2021, have greatly helped SNF patient care by allowing providers to concentrate their time, personnel and other resources on both the traditional types of patients and the influx of pandemic-affected patients. The data below show the SNF field's significant concentration on treating active-COVID-19 and post-COVID-19 patients. The active-COVID-19 rates are based on SNF claims, and the COVID-19-affected rates are based on claims from all settings, both of which grew between April 2020 and December 2020. In December 2020, these groups of patients accounted for more than one out of two SNF patients.

COVID-19 SNF Cases: April 2020 through Dec. 2020
Percent of all SNF Cases; COVID Status from Both SNF and Prior Services Claims



Sources: Medicare fee-for-service claims, Centers for Medicare & Medicaid Services, Chronic Conditions Data Warehouse, https://www2.ccwdata.org/web/guest/home.

In addition, the data below show the change in volume, case-mix index and average length of stay (ALOS) from the 12-month period preceding the PHE to the first 12

months of the PHE[1] for patients discharged from referring hospitals to post-acute care settings, including SNFs. COVID-19 materially changed these factors, inducing a substantial drop in patient volume, as well as increases in average acuity and ALOS. These data, as well, indicate that COVID-19 continues to affect the SNF patient population, and underscore the need for waivers to continue through the PHE.

Inpatient PPS Discharge Destination Data on COVID-19 Cases
Rate of Change from Pre-PHE 12 months vs. PHE 12-month Period

Inpatient Hospital Discharge Destination	Case Volume	Case-mix Index	Average Length of Stay
All Inpatient PPS Discharges	-17.6%	6.3%	8.2%
Home Health	-6.1%	4.6%	8.7%
SNF	**-30.2%**	**2.7%**	**8.3%**
Inpatient Rehabilitation Fac.	-11.7%	3.2%	7.9%
Long-term Care Hospital	-12.9%	7.1%	12.4%

Source: Medicare fee-for-service claims, Centers for Medicare & Medicaid Services, Chronic Conditions Data Warehouse, https://www2.ccwdata.org/web/guest/home.

Discussion of Future Parity Adjustment

As noted, the AHA appreciated that CMS did not propose an addition to the "parity adjustment" designed to ensure budget neutrality of the PDPM. We appreciate this opportunity to weigh in on how to design a future modification, as well as approaches to phase-in such an adjustment. In the FY 2020 final rule, CMS applied a "parity adjustment"[2] to the first year of the PDPM payments to attempt to set aggregate spending equal to what they would have been under the prior case-mix system. However, in this rule, CMS states that "rather than simply achieving parity, the FY 2020 parity adjustment may have inadvertently triggered a significant increase in overall payment levels under the SNF PPS." In fact, the rule notes that the most currently available data indicate that fee-for-service Medicare will pay 5% more ($1.7 billion) in FY 2020 than the agency otherwise would have paid to SNFs. Further, the rule concludes that "…a recalibration of the PDPM parity adjustment is warranted to ensure that the adjustment serves its intended purpose to make the transition between RUG-IV and PDPM budget neutral."

[1] A comparison of the PHE period of Jan. 27, 2020 to Jan 26, 2021 versus the pre-PHE period of Jan. 27, 2019 through Jan 26, 2020.
[2] The FY 2020 final rule applied a multiplier of 46% to the PDPM case mix indices, using FY 2018 claims as the base, to strive to achieve budget neutrality relative to the prior "RUG-IV" case-mix system, assuming no changes in the population, provider behavior and coding.

Based on feedback from our members, AHA would support a future, prospective modification of the FY 2020 parity adjustment, if warranted, if it delays its implementation for at least one year and is phased in if material in size. This combination of delay and phase-in strategies would help SNFs plan and budget for the change, including preparation for the cost of this cut in combination with other PHE-response and longer-term recovery costs.

Potential Future Recalibration Method. When considering how to recalibrate the FY 2020 parity adjustment, the rule clarifies that the relevant issue is determining whether the SNF case-mix distribution is distinctly different from what it would have been were it not for the COVID-19 PHE. In other words, while different people were able to access the Part A SNF benefit because of the 3-day stay and other PHE waivers, the agency must consider whether the relative case-mix distribution of beneficiaries in FY 2020 differed from what it would have been absent the PHE.

With regard to FY 2020 payments, CMS estimates that Medicare paid 5.3% more under PDPM than it would have under the prior model, when considering the full SNF population. If those cases using a COVID-19 waiver or diagnosed with COVID-19 are eliminated, the agency estimates that the increase would have been 5.0%. Given that these rates are similar, CMS believes that it would be more appropriate to pursue a recalibration using the subset population exclusive of COVID-19 waiver patients and patients diagnosed with COVID-19. As such, the rule discusses, but does not propose, a 5.0% reduction in the PDPM parity adjustment factor from 46% to 37%. Hypothetically, if this adjustment were applied for FY 2022, CMS estimates a reduction in SNF spending of approximately $1.7 billion.

We urge CMS to apply extra diligence to ensure that not only are all COVID-19 cases excluded from their ongoing analyses, but also cases indirectly affected by the pandemic. Applying the full scope of reasonable exclusions will help ensure that any future modification of the FY 2020 parity adjustment accurately depict the impact of PDPM in its first year, apart from the impact of the PHE.

Specifically, CMS should consider excluding:

- Cases, such as bronchitis and acute pneumonia patients, for which SNFs treated greater than normal volumes in FY 2020, and that had a COVID-19 code during the prior hospital stay;
- Cases that had an unusually long prior hospital length of stay and a COVID-19 code in the referring hospital;
- Other FY 2020 COVID-19-affected cases, especially during the early months of the PHE, that may not have an official COVID-19 code due to evolving coding guidelines combined with SNFs' extreme operational disruptions at that time. This group should be identified with the help of a FY 2020 coding accuracy validation;

- Cases that were already admitted when PDPM took effect on Oct. 1, 2019, for which substantial PDPM inflation factors were applied to adjust payments to fit the framework of the new case-mix system – such as cases with non-therapy ancillary services adjustment, who tend to be sicker and most costly; and
- The substantial portion of patients admitted directly to SNF isolation during the PHE, which actually may be COVID-19 cases that were not picked up by official coding.

Proposed Revising and Rebasing of the SNF PPS Market Basket and Proposed Forecast Error Adjustment

CMS proposes to shift the SNF PPS from a FY 2014-based market basket to one utilizing FY 2018 data. While maintaining a relevant market basket is a fundamental requirement for a well-functioning PPS, given the magnitude of current and expected ongoing SNF strains from the PHE, for the FY 2022 update, we ask CMS to explore the temporary use of more heavily-weighted market-basket elements to account for COVID-19-influenced cost increases, especially for both in-house and contract labor costs and capital costs. Also warranting close examination are the additional nursing and other costs that may be under-detected due to room-sharing by more than one COVID-19-positive patient that was required by space constraints and/or isolation room shortages, which can trigger an under-assessment of nursing and other resource intensity.

In addition to these proposed market basket updates for FY 2022, CMS proposes to offset the 2.3% market basket with a negative 0.8% market-basket forecast error adjustment. The forecast error cut would address the difference between the projected and actual market basket for FY 2020, 2.8% and 2.0%, respectively. While we also generally support the forecast error concept for this PPS, given the scale of the COVID-19-driven disruption that occurred in FY 2020, and the resulting atypical COVID-19 claims, the AHA raises concerns about the reliability and timing of the proposed 0.8% cut.

Further, this significant cut would have a substantial impact on SNF operations, and, ultimately, SNF patients – especially given the expectation for the SNF COVID-19 recovery to be underway in FY 2022. As such, we encourage CMS to proceed with caution and additional analyses prior to finalizing these changes.

QUALITY REPORTING-RELATED PROPOSALS

SNF Quality Reporting Program (QRP)

The Affordable Care Act mandated that reporting of quality measures for SNFs begin no later than FY 2014. Failure to comply with SNF QRP requirements will result in a 2.0 percentage point reduction to the SNF's annual market-basket update. For FY 2022, CMS requires the reporting of 13 quality measures by SNFs.

CMS proposes to add two measures to the FY 2023 SNF QRP. In addition, CMS proposes updates on publicly reported data in light of the COVID-19 PHE and seeks feedback on several requests for information (RFIs).

While the AHA appreciates that the proposed measures are intended to address important topics, including COVID-19 vaccination among health care personnel and healthcare associated infections (HAIs) acquired in SNFs, we do not believe that either measure should be adopted for the FY 2023 SNF QRP. If CMS is intent on implementing the COVID-19 vaccination measure, we would urge the agency to either make the measure voluntary for the FY 2023 program, or delay implementation by at least one year.

FY 2023 Measurement Proposals

Adoption of SNF Healthcare-associated Infections (HAIs) Requiring Hospitalization Measure. CMS proposes to adopt this outcome measure that uses hospital claims to calculate HAIs ostensibly acquired during the proximal SNF stay. There is no doubt that preventing HAIs in SNFs is a top priority, and we agree 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 parsimonious and meaningful set of quality measures which will inform both care delivery and patient choice, we have several concerns regarding the specifications and concept of this measure. **As we have commented several times before during the course of this measure's development, 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 proposed measure.**

First, 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 this 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; this data is based on certain counts of bacteria or certain test results gathered based on very detailed instructions about what cases to include or not in denominator and clinical definitions that only an infection prevention expert or other qualified clinical personnel can interpret. This process not only ensures data integrity, but also 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 two to three year lag between when claims are submitted and when data is used to inform measure performance.

Additionally, CMS itself has found that administrative claims data is not reliable to inform HAI measure performance. For example, in a 2012 reliability analysis, CMS' contractor found that several claims-based HAC (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 called into question 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 leave out at least 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. 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 ensures that providers know quickly which patients are infected, and can rapidly take the infection control steps needed to protect other patients and staff from infection. To be blunt, no successful HAI reduction effort can afford to wait two to three years to have incomplete claims-based data to inform it. And for the reasons we describe below, this claims-based measure is likely to be a poor reflection of their actual performance.

Additionally, there are several factors at the patient and provider level that influence outcomes but 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 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. However, the end goal is better, safer care for all patients, and for that reason, we encourage CMS to deploy quality improvement support to help accelerate progress on reducing HAIs in SNFs.

This is a model that has worked incredibly well for hospitals, as evidenced by the rapid progress of CMS' 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 is up to that critically important task. It also is 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.**

Adoption of COVID-19 Vaccination among Health Care Personnel (HCP) Measure. This measure would calculate the percentage of HCP eligible to work in the facility for at least one day during the reporting period who received a complete vaccination course. The measure would exclude persons with medical contraindications to the COVID-19 vaccination as described by the Centers for Disease Control and Prevention (CDC), but otherwise all facility personnel — including licensed independent practitioners affiliated with but not directly employed by the facility and students, trainees and volunteers — are included in the denominator, regardless of clinical responsibility or patient contact. The measure would be reported using CDC's NHSN Healthcare Personnel Safety Component submission framework.

The AHA strongly supports COVID-19 vaccinations of both HCPs and the communities they serve. We have worked closely with our members and the federal government to encourage vaccination to help protect both patients and our health care workforce from this crippling disease. Health care facilities have made remarkable progress in vaccinating large proportions of their teams in a short timeframe, and are working hard to close any remaining gaps. Notwithstanding the remarkable scientific achievement of having three available and highly effective COVID-19 vaccines, we are barely six months into deploying them. The underlying scientific evidence about how to implement the vaccines continues to evolve, and there remain important unanswered questions that would affect both the design and feasibility of any HCP vaccination measure. To list just a few, for how long do the vaccines confer immunity? How frequently might booster shots be required? Should one receive the same type of booster shot as the original shot? Will vaccine supply remain sufficient across the nation to ensure all HCP can receive it?

None of these questions detracts from the importance of encouraging COVID-19 vaccinations. However, the answers to all of these questions are of foundational importance to building a meaningful, accurate and fair performance measure whose results would be shared publicly. The AHA is concerned that a premature mandate to report this measure would lead to unpredictable shifts in reporting requirements that

would prove disruptive to hospitals, and result in data that are unhelpful to policymakers, the public and health care providers.

Due to the unique nature of the COVID-19 pandemic and the limited experience the nation has with the vaccine products currently available, we do not recommend implementing this measure for mandatory reporting this year, as its use could have negative unintended consequences and might not be the most useful tool to promote vaccination. Instead, the AHA recommends that CMS either delay adoption of the measure for at least one year (i.e., until Oct. 1, 2022), or adopt the measure for voluntary reporting for at least the first year to allow time for the issue described below to be addressed. Any voluntarily reported data should not be publicly reported.

In its rationale and explanation of the measure's design, CMS relies heavily on the specifications and experience with the Influenza Vaccination among Healthcare Personnel measure (NQF #0431). However, the circumstances around use of the COVID-19 vaccine are not entirely comparable to those of the influenza vaccine, as COVID-19 and the vaccines have had a short and at times, unpredictable implementation. The three vaccine products on the market — from Moderna, Pfizer, and Johnson and Johnson — are currently only available under the Food and Drug Administration's (FDA) emergency use authorization. While we are confident in the safety and efficacy of these products and at least one is likely to receive full FDA approval imminently, we find it to be incongruous to adopt a measure into federal quality reporting programs that assesses the use of a product that has not yet received full federal approval.

Another important distinction between the measure proposed in this rule and the influenza measure already in use is that the COVID-19 vaccination measure has not gone through the rigorous testing and NQF endorsement review process to which other measures adopted in CMS quality reporting programs are subject. The measure was presented to the NQF's Measure Applications Partnership (MAP) as a concept rather than as a measure ready for implementation; CMS leadership explained during the MAP meetings that the agency was bringing forward a measure that wasn't "fully fleshed out" in anticipation of incorporating it into rule-writing in 2022 at the earliest.

While the measure is designed nearly identically to the flu vaccine measure in terms of its calculation and reporting structures, many questions about the specifics of the COVID-19 measure remain (questions that might be answered during the testing and NQF endorsement processes). For example, what are the long-term plans for use of this measure in terms of its reporting period? The flu vaccine measure assesses vaccinations during "flu season," which is defined as October through March; will there be a similar "COVID-19 season," and how will reporting interact with that of the flu measure? Is this measure in alignment with other COVID-19 vaccination measures under consideration, such as the Merit-based Incentive Payment System measure that

was reviewed by the MAP which assessed patients who received at least one dose (as opposed to a complete course)?

Considering the magnitude of changes in the circumstances regarding COVID-19 vaccinations in 2021 alone, additional questions concerning the logistics of this measure may arise. The availability of doses played a major role in vaccination status earlier this year; for example, safety violations at a single plant resulted in millions of unusable doses of the Johnson and Johnson vaccine. If the supply chain were disrupted again, health care facilities could be unable to ensure the vaccination status of their employees through no fault of their own. The nation has not yet completed the first wave of complete vaccinations — as of this writing, less than 40% of Americans were fully vaccinated — and thus we have not yet begun to address needs or logistics for "booster" shots. Because of the rapidly changing circumstances in which the COVID-19 vaccines are being deployed, we believe it is unwise to permanently adopt this measure into federal quality reporting programs at this time.

In addition to these logistical concerns, CMS also should consider the potential unintended consequences of the use of this measure. The reporting burden associated with this measure may be high depending on how it interacts with other COVID-19 data reporting requirements. Certain health care settings (including SNFs as well as inpatient psychiatric facilities) do not currently use NHSN to report data for quality reporting programs, so the introduction of this measure would require adjustments in workflow for which CMS would need to provide significant technical support. In addition, use of this measure may cause providers to amend other employee-facing policies, which take time to implement.

Moreover, while the measure does not directly compel facilities to ensure that their employees are vaccinated, publicly reporting performance on this measure might incent facilities to adopt mandatory vaccination policies for their personnel. Clearly, a vaccination mandate could be beneficial to measure performance. Yet, the decision about whether to implement a mandate is complex, and in some cases, the decision may be beyond the control of health care facilities. Already, multiple states have introduced or passed legislation prohibiting discrimination based on COVID-19 vaccination status; other existing state laws might also run afoul of mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate the vaccine could be at a systematic performance disadvantage on the measure. We also urge CMS to be mindful of other complex issues that could shape any mandatory vaccination approach. For example, the measure only excludes patients who do not get the vaccine due to medical contraindications. According to the Equal Employment Opportunity Commission, employers must provide a reasonable accommodation if an employee's sincerely held religious belief, practice or observance prevents them from receiving the vaccination; this policy seems to conflict with the specifications of the proposed measure. A mandatory vaccine policy — with suitable exceptions and employee protections — might be appropriate, but until we have more than eight months of data on the vaccine's safety and side effects, we are unsure whether

indirectly encouraging through the mandatory public reporting of COVID-19 vaccination rates is judicious.

The COVID-19 pandemic is not the last public health emergency this nation is likely to face, but our national response will have long-lasting effects on policy. The AHA is concerned about the precedent of adopting a measure assessing COVID-19 vaccination of HCP under these circumstances, and would thus recommend that CMS reconsider adopting the measure during this rulemaking cycle. **Instead, CMS should either delay adoption of the measure for at least one year or adopt the measure for voluntary reporting only — without publicly reporting performance — for at least the first quarter of the measure's use (beginning Oct. 1 of this year) to allow for time to answer the questions raised above regarding feasibility, validity, and the incidence of any unintended consequences.**

Request for Information on Health Equity. In light of the Administration's efforts to address equity — specifically health equity — the agency requests information on revising several CMS programs to make reporting of health disparities based on social risk factors and race and ethnicity more comprehensive and actionable for providers and patients. Specifically, the agency seeks recommendations for quality measures or measurement domains that address health equity as well as the collection of other standardized patient assessment data elements (SPADEs) that address gaps in health equity in post-acute care quality reporting programs.

The AHA applauds CMS' focus on addressing disparities in health outcomes by thoughtfully considering how to best leverage data; we agree providing equitable care begins with understanding the unique needs of patients. Data and analytics allow hospitals, health systems, and post-acute care providers to see the challenges and barriers some patients may face when accessing care, and can help pinpoint where resources may be deployed to address gaps in access or quality of care as well as provide deeper insights to instruct and inform intentional actions by leadership and clinical teams. Because of this, the AHA and its Institute for Diversity and Health Equity recently launched the first in a new series of toolkits designed to help hospitals and health systems make progress in advancing their health equity agendas. This toolkit, Data-Driven Care Delivery: Data Collection, Stratification and Use, addresses the importance of segmenting and leveraging patient data to tackle disparate care outcomes and drive improvements. We hope that we can work closely with CMS and the entire Administration to develop best practices based on what our members have told us.

As CMS develops its quality measurement approach to health equity, we encourage the agency to strive for consistency and alignment across all of its provider measurement programs, and with other entities within the federal government. One way to do this is to consider data collection across the continuum of care. In the FY 2020 proposed rules for the IRF, long-term care hospital, SNF and home health prospective payment systems, CMS adopted seven SPADEs addressing social determinants of health

(SDOH). In our comments on those rules, we requested clarity from CMS on the potential future uses of these elements and the requirements around data collection for certain elements, such as the frequency with which those SPADEs are collected. In addition, we were unsure that the response options under the race data element were the right ones. It appears that some of the categories are not consistent with those used in other government data collection practices, like the Census or the Office of Management and Budget, and are not consistent with the recommendations made in the 2009 Institute of Medicine report on Standardized Collection of Data on Race, Ethnicity and Language. Considering that health is affected by factors and circumstances not only adjudicated under the Department of Health and Human Services, it is vital that CMS work closely with other agencies and government actors to ensure that we are all collecting the same — and the right — data in the same — and the right —way.

Further, regarding CMS' request for feedback on additional SDOH SPADEs, we would urge the agency to gain more operational experience with these seven newly added elements before adopting additional data fields. These elements have not been in use for an entire year, so the feasibility and usefulness of the information gleaned from their use remains to be seen. As in the rest of its quality measurement enterprise, CMS should strive for a streamlined and parsimonious set of data elements to increase the likelihood of collecting precise information in the most efficient way possible. Indeed, we previously shared our concerns about the rigidity of the data collection process for certain SPADEs in our comments on the FY 2020 IRF PPS proposed rule, and would encourage the agency to consider more flexible timeframes for collecting SDOH SPADEs going forward.

Finally, many of CMS' suggestions, programs and proposals regarding disparities are defined around either race and ethnicity or dual eligibility for Medicare and Medicaid as a proxy for income. While there is no doubt these factors are vital to assess, the agency — and providers — need to explore other demographic and social risk factors as well. These include, but are not limited to, sexual orientation, gender expression, education and literacy, veteran status, disability status, housing, social isolation, and community resources. These data often rely on patient self-reporting, and stakeholders are still learning what data elements are the most useful and practical to collect, analyze and use. We would encourage CMS to engage with stakeholders to understand what opportunities there may be to promote greater consistency and standardization of approaches.

RFI on Digital Quality Measures (dQMs) and Fast Healthcare Interoperability Resource (FHIR). In this rule, CMS outlines the agency's general considerations for the future development and staged implementation of a cohesive portfolio of dQMs across quality programs, agencies, and private payers, as well as the potential use of FHIR for dQMs within quality programs. The AHA agrees that a digital and interoperable quality enterprise is a laudable goal that could have positive and far-reaching effects of patient outcomes and experience. We also support the potential use of FHIR, as this standard

is easier to implement and more fluid than many other available frameworks. **However, we encourage CMS to hone its approach to transforming its quality measurement enterprise by more clearly defining the goals and expectations for providers and considering the specific needs and capabilities of post-acute care providers and their patients.**

The seminal statute for health information technology, the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009, resolved to spend $25.9 billion to promote and expand the adoption of health IT; to implement the requirements of the HITECH Act, CMS offered incentives to eligible professionals and hospitals that adopt and demonstrate the meaningful use of electronic health records (EHRs). However, long-term care and post-acute care providers were not eligible for the EHR Incentive Programs (not known as the Promoting Interoperability Programs) under the Act. In its 2019 RFI that accompanied the Interoperability and Patient Access proposed rule, CMS largely attributed the slow rate of EHR adoption in post-acute care settings to the lack of federal incentives available to these providers.

In addition to this lag, the experience with various health IT capabilities in post-acute care is heterogeneous; while some providers have been able to successfully incorporate health IT with higher levels of sophistication, including certified EHR technology (CEHRT), others are using technologies with fewer capabilities for digital exchange. The shortages in health IT professionals and resources dedicated to health IT are particularly dire for post-acute care providers, so any new requirements for attestation to digital capabilities will result in even more competition for vendor attention — both among post-acute care providers and between post-acute and general acute care providers.

Because of these challenges, any approach to digital quality measurement in post-acute care will have to be nuanced and gradual. We encourage CMS to consider developing a “glide path” for post-acute care provider participation in digital quality measurement, one that provides technical assistance for providers who are less advanced in their health IT capabilities as well as more opportunities for achievement for those who are well on their way. **Adoption and implementation of health IT systems like CEHRT is not like flipping a switch; it involves painstaking and thoughtful groundwork to establish an infrastructure — including security and personnel as well as physical investments — that can support highly technical requirements.** A definition of dQMs must be understandable for those providers who do not have as robust a technology infrastructure so that they can work to someday achieve interoperability rather than abandon hope because the future is daunting and expensive.

We encourage CMS to further hone its definition of dQMs by setting clear and specific parameters for what the agency hopes to achieve and what it expects of participating providers. For example, what would the agency do differently to “transform” its quality measurement enterprise in order for the measures used in various quality reporting programs to meet the definition of dQMs? The definition proffered in the RFI is quite

broad, and lists data sources including administrative systems, electronically submitted clinical assessment data, case management systems, EHRs, instruments (for example, medical devices and wearable devices), patient portals or applications (for example, for collection of patient-generated health data), health information exchanges (HIEs) or registries, and other sources." Using this definition, it could be argued that SNFs, IRFs, LTCHs, and home health agencies are already reporting dQMs, and thus no "transformation" is necessary. On the other hand, it also could be argued that the agency, in seeking to fully transition to dQMs by 2025, expects providers to be able to interact with all of these data sources and thus take on more than a decade's worth of un-funded work in just a few years. In order to plan for the future of digital quality measurement, CMS should more clearly define what it expects that future to look like for all providers, specifically post-acute care providers, and how those expectations differ from the status quo.

The AHA and our members are excited to work with CMS to build their digital quality measurement enterprise, and we would be happy to collaborate on more specific plans for the future.

SNF Value-based Purchasing (VBP) Program

The Protecting Access to Medicare Act (PAMA) of 2014 requires CMS to establish a VBP program for SNFs beginning in FY 2019. The program must tie a portion of SNF Medicare reimbursement to performance on either a measure of all-cause hospital readmissions from SNFs or a "potentially avoidable readmission" measure; currently, the VBP program is informed by the Skilled Nursing Facility 30-day All-Cause Readmission Measure (SNFRM). A funding pool is be created by reducing each SNF's Medicare per-diem payments by 2%; as permitted under the statute, CMS distributes 60% of the pool back to SNFs in the form of incentive payments. In this proposed rule, CMS proposes to suppress the use of the SNFRM for the FY 2022 VBP program in light of the COVID-19 PHE and instead assign performance scores and uniform payment incentive adjustments.

Measure Suppression and Performance Scoring for FY 2022. CMS notes in the proposed rule that the agency recognizes the effects that the COVID-19 pandemic has had on SNF readmission rates, and that these effects are not uniform across the country. Therefore, the agency does not wish to penalize SNFs based on measure scores that have likely been distorted by the pandemic and are not reflective of the quality of care. In this rule, the agency proposes to adopt a policy for the duration of the PHE allowing it to suppress SNF readmission measure data for use in the VBP program if the agency determines that the PHE has affected performance significantly. Following this policy, CMS proposes to suppress the all-cause hospital readmissions measure for the FY 2022 SNF VBP program year. As a result of this policy, the agency would assign all eligible SNFs a uniform performance score of zero, which would yield a payment adjustment of 1.2% —or 60% of the 2% withhold, which would still be applied across the board. SNFs with fewer than 25 eligible stays would have a neutral payment adjustment.

The AHA acknowledges CMS faces statutory constraints in accounting for the impact of the COVID-19 pandemic in the SNF VBP program. As required by the PAMA, the SNF VBP program results in savings to the Medicare program. In normal years, that means some SNFs experiences payment decreases in order to fund both bonuses to higher scoring SNFs and savings to the Medicare program. That means a "hold harmless" approach – such as the one CMS has proposed for the budget neutral hospital value-based purchasing program for FY 2022 – is likely infeasible for SNF VBP. In addition, payment adjustments are currently based on performance on a single, imperfect measure, and CMS is not yet authorized to add new measures to the SNF VBP. This means CMS cannot simply substitute different measure(s) that may be less affected by the pandemic. Because of these obstacles, we do not oppose the concept of the agency's proposals.

However, we would like to raise a few alternatives and suggestions for the agency to consider, both for its proposals for the FY 2022 program year as well as in the future. First, we strongly urge CMS to pay out the maximum 70% of the withhold for FY 2022, which is allowed under PAMA: "the total amount of value-based incentive payments under this paragraph for all skilled nursing facilities in such fiscal year shall be greater than or equal to 50%, but not greater than 70%, of the total amount of the reductions to payments for such fiscal year." CMS chose to pay out 60% of the withhold in previous rulemaking, but we believe the agency could offset at least some of the losses from the program this way.

In addition, we encourage CMS to consider excluding patients from the eligible case count who had a COVID diagnosis; this method would likely lead to many more SNFs having an insufficient number of cases, and thus receiving a neutral payment update (instead of a penalty). CMS also could consider basing payment adjustments on data from the 2019 performance period. While this method would result in payment based on actual performance, which might be fairer than applying a uniform adjustment regardless of performance, it would result in some providers being penalized twice even if they improved in 2020.

The use of the SNF VBP program to generate savings is a statutory design to which the AHA has long objected, and we again acknowledge the extent to which this design limits what CMS can do to provide SNFs with appropriate relief in the midst of the COVID-19 pandemic. However, we encourage CMS to explore these alternatives to mitigate the adverse impact of an already deeply flawed program.

Measures to Add to the SNF VBP Program. The Consolidated Appropriations Act of 2021 allows the HHS Secretary to apply up to nine additional quality measures for the SNF VBP program. In this rule, CMS lists measures and clinical topics for consideration for the SNF VBP program and requests feedback on which measures are appropriate and whether the additional measures should require SNFs to collect data on all residents in the facility, regardless of payer.

When choosing measures for the VBP program, we encourage CMS to focus on those that have received NQF endorsement. The endorsement process involves rigorous review of the measure's specifications as well as conceptual and logistical details; without this review and approval from the measurement experts at the NQF, a measure may be implemented into a program without assurances of its validity and reliability and may carry negative unintended consequences. CMS is not obligated to use only NQF-endorsed measures in its programs, but we believe that doing so would result in a more reliable set of quality indicators.

Further, the majority of measures used in a VBP program should be outcomes-focused in order to truly achieve high-value care for patients. Certain measures under consideration in this rule are process measures with unclear links to value, including Transfer of Health Information to the Provider, while others don't assess performance that would matter to patients, like Medicare Spending per Beneficiary. Instead, the SNF VBP program should focus on high-priority topics that can be evaluated using evidence-based measures that provider behavioral influences directly: patient safety, mortality and complications, appropriateness of care, and outcomes including functional independence, improvement or maintenance.

Thank you for the opportunity to comment on this proposed rule. Please contact me if you have questions or feel free to have a member of your team contact Rochelle Archuleta, AHA's director of policy, at rarchuleta@aha.org, on any payment-related issues, and Caitlin Gillooley, AHA's senior associate director of policy, at cgillooley@aha.org, regarding any quality-related questions.

Sincerely,

/s/

Stacey Hughes
Executive Vice President