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Advancing Health in America

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June 28, 2020

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

RE: CMS-1752-P. *Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Proposed Changes to Medicaid Provider Enrollment; and Proposed Changes to the Medicare Shared Savings Program.*

Dear Administrator Brooks-LaSure:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 240 long-term care hospitals (LTCHs), 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 LTCH provisions in the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2022 proposed rule for the inpatient and LTCH prospective payment systems (PPS). We are separately submitting comments on the rule's inpatient PPS proposals.

This letter focuses on the LTCH provisions in the rule and provides an update on the LTCH role in the COVID-19 pandemic response. **The AHA supports many of the provisions in the rule, including the proposed use of FY 2019 claims as a basis for calculating the FY 2022 payment update, the proposal to require state Medicaid programs to enroll all eligible Medicare providers, and the overall objectives of the requests for information on health equity and digital quality reporting. However, we have concerns with other issues, such as the FY 2023 implementation of the proposed COVID-19 vaccination quality measure.**

THE LTCH ROLE IN THE NATIONAL COVID-19 RESPONSE

The AHA appreciates the proposed rule's streamlined LTCH provisions, which allow LTCHs and their partners to focus on local COVID-19 responses and, in some areas, pandemic recovery. In multiple ways, LTCHs provided care for COVID-19 patients and otherwise worked to relieve the virus's strains on the health care delivery system.

For example, LTCHs:

- treated medically-complex patients with active virus;
- treated high-acuity patients transferred from overwhelmed general acute-care hospitals – including patients recovering from the virus; and
- are currently treating patients with long-term clinical COVID-19-related needs that align with LTCHs' unique competencies.

LTCHs' specialization in treating chronically critically ill patients and the composition of their clinical teams, which are designed with a focus on treating high-acuity pulmonary and other conditions, have proven to be well-suited to meeting the needs of COVID-19 patients, as well as patients recovering from the virus who have medically-complex needs. In particular, the LTCH field, where needed, demonstrated its ability to quickly ramp up capacity to function at levels similar to those of general acute-care hospitals. This capacity includes providing high-flow oxygen treatment, care in pressurized rooms, high levels of infection control, and close medical monitoring in critical care units – many of which were designated entirely for active COVID-19 patients.

In addition, and most recently, LTCHs are providing valuable care for those "long-haul" patients suffering from COVID-19's aftereffects, such as scarring of the lungs, restrictive lung disease, and other complex symptoms similar to those experience by patients with post-ICU syndrome. As we are learning, this population of patients includes those with material and persistent deficiencies beyond 12 weeks, and even up to a year or longer, from the actual inception of the virus.

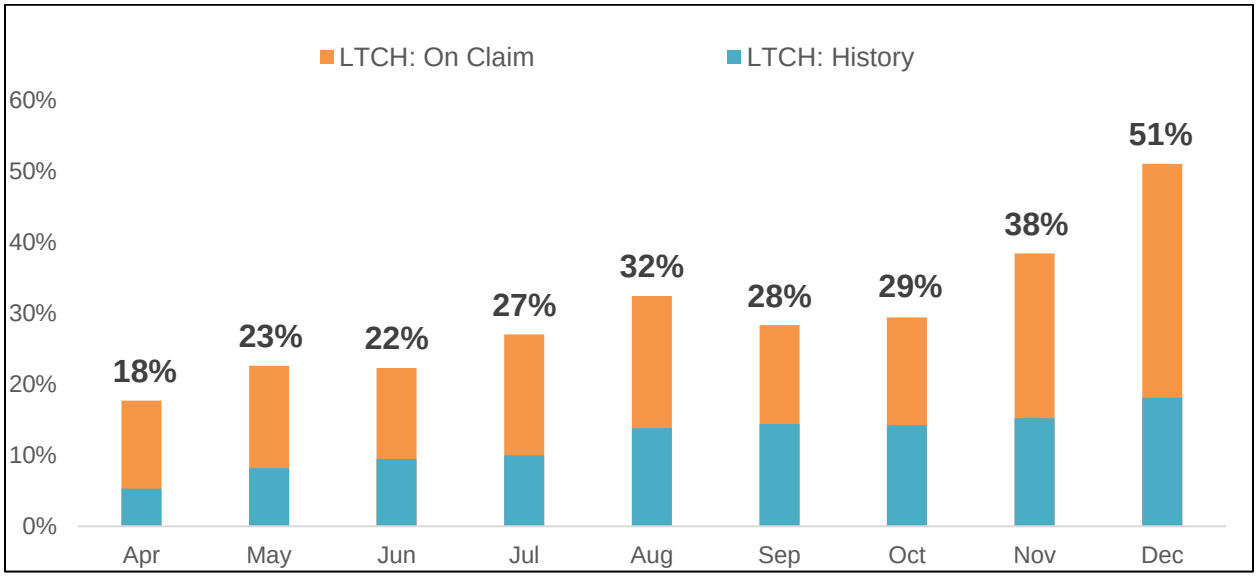
The public health emergency (PHE) flexibilities implemented by CMS in FY 2020, several of which were authorized by Congress and continue in FY 2021, greatly facilitated timely patient transfers to LTCHs and helped the field concentrate its time, personnel and other resources on both the traditional types of patients and the influx of pandemic-affected patients.

The data below show the LTCH field's significant concentration on treating active-COVID-19 and post-COVID-19 patients. Specifically, it shows the percentage of LTCH cases with a COVID-19 diagnosis during the patient's LTCH stay, as well as the percentage of cases with a COVID-19 diagnosis prior to the LTCH stay[1]. Both groups increased from April 2020 through December 2020. In December 2020, these

[1] To identify cases with a COVID-19 diagnosis prior to the LTCH stay, and to avoid double-counting cases, all non-COVID LTCH claims were checked to determine whether the patient had a history of COVID-19 prior to an LTCH admission, based on claims from nine settings – inpatient, outpatient, carrier (physician), durable medical equipment (DME), LTCH, IRF, SNF, HH and hospice.

groups of patients accounted for about one out of every two LTCH patients – a rate that clearly demonstrates the concentrated and sustained effort by the field to contribute to pandemic recovery.

Percent of LTCH Cases with COVID-19 Diagnosis, April 2020 through December 2020



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 following data show the change in volume, case-mix index (CMI) and average length of stay (ALOS) for patients discharged from referring hospitals to post-acute care settings, including LTCHs, from the 12-month period preceding the PHE to the first year of the PHE. For LTCHs, COVID-19 changed these factors, resulting in a large drop in patient volume, as well as the most significant increases in average acuity and ALOS of any post-acute care destination. These data convey the magnitude to which the pandemic continues to dramatically affect the overall LTCH patient population. In fact, it remains to be seen what the post-pandemic landscape will look like for LTCHs, with many anticipating the inability to fully return to the pre-PHE environment.

Percent Change from Pre-PHE to PHE Period, by IPPS Discharge Destination[2]

IPPS Discharge Destination	Case Volume	CMI	ALOS
All Inpatient PPS Discharges	-17.6%	6.3%	8.2%
To HH	-6.1%	4.6%	8.7%
To SNF	-30.2%	2.7%	8.3%
To IRF	-11.7%	3.2%	7.9%
To LTCH	**-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.

USE OF FY 2019 CLAIMS DATA IN RATE SETTING

CMS states that both the FY 2020 claims and the FY 2019 cost report data, which typically would have been used for rate setting in FY 2022, were impacted by the COVID-19 PHE and are highly unusual compared to past years. CMS specifically cited how their use in rate setting results in an aberrant outlier fixed-loss amount, MS-LTC-DRG relative weights, and case mix. For example, the fixed-loss threshold was nearly 20% higher based on 2020 data compared to 2019 data.

Accordingly, CMS proposes to use FY 2019 claims and FY 2018 cost report data in place of where it would have ordinarily used FY 2020 claims and FY 2019 cost reports. **The AHA supports CMS' proposal to use FY 2019 claims and FY 2018 cost report data for FY 2022 rate setting and appreciates its recognition of the unusual nature of the FY 2020 data. That said, AHA's support of this methodology only pertains to the proposed FY 2022 rates and weights. The data used in future years' rulemaking should be revisited on a year-by-year basis.**

PROPOSED CHANGES TO THE CC/MCC LIST FOR UNSPECIFIED CODES

For FY 2022, as another interval step in the comprehensive review of the severity designations of ICD-10-CM diagnosis codes, CMS is soliciting comments on adopting for FY 2022 a change to 3,490 "unspecified" diagnosis codes currently designated as either CC or MCC, where there are other codes available in that code subcategory that further specify the anatomic site, to *non-CC*. Table 6P.2a of this proposed rule includes the list of ICD-10-CM unspecified diagnosis codes with data for impact on resource use. If approved, the change would affect the severity level assignment for 4.8% of the ICD-10-CM diagnosis codes. The net result of these potential changes to the Version 39 ICD-10 MS-LTC-DRG MCC/CC list, for the 72,621 diagnosis codes in the ICD-10-CM classification, would be a decrease of 507 (3,278 – 2,771) codes designated as an MCC, a decrease of 2,983 (14,679 – 11,696) codes designated as a CC, and an increase of 3,490 (58,154 – 54,664) codes designated as non-CC.

[2] 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.

We urge CMS to delay the downgrading of the severity designation of "unspecified" codes to non-CC to allow further analysis; provider education; system updates; potential updates of the *ICD-10-CM Official Guidelines for Coding and Reporting*; and training of coding professional for the reasons noted below. Some members have already noted that the change will result in significant losses and will require time to implement mitigation plans. We therefore request that the implementation be delayed and phased over a two-year period.

- While the AHA continues to support complete and accurate documentation to support clinical coding, the concept of laterality (right side or left side) would not affect the resources required to treat patients, with the exception of bilateral conditions. We further note that laterality is *not* one of CMS' long- standing criteria for determining the severity level of a condition. We request that CMS provide insight pertaining to how conditions' laterality impact the severity of the diagnosis, especially with internal locations not visible to the eye. The condition/diagnosis itself is still being addressed and treated as applicable.
- If the principal diagnosis is unrelated to the secondary "unspecified" diagnosis, there should not be a requirement to perform medically unnecessary tests or procure from other facilities prior medical records to determine laterality.
- The Medicare population involves an elderly population that tend to have multiple providers, chronic conditions and often experience confusion. It may not be feasible to expect documentation to reflect laterality for chronic conditions such as neoplasms; additionally, patients with dementia may not be able to provide accurate histories.
- *ICD-10-CM Official Guidelines for Coding and Reporting* Section I.B. 14 states "Code assignment is based on the documentation by the patient's provider (i.e., physician or other qualified healthcare practitioner legally accountable for establishing the patient's diagnosis)." If the provider (as defined by the guidelines) documentation does not specify the side affected, hospitals would be required to conduct administratively burdensome physician queries in order to capture the more specific code to qualify for a CC or MCC.
- In our role as one of the ICD-10 Cooperating Parties responsible for the development of the Official Coding Guidelines, we are collaborating on the potential revision of the guidelines to allow coding of the more specific laterality, based on the more specific documentation from other clinicians involved in the care of the patient, such as nurses. If approved, the change would be effective FY 2022, which would require further education of professional coders.
- While many hospitals have robust clinical documentation improvement programs, some may not have explicitly focused on documentation of laterality as it did not affect conditions' severity level.
- **We request CMS reconsider the inclusion of neoplasms in the list of "unspecified" sites or limit it to externally visible neoplasms.** While the neoplasm may still be under active treatment, the specific side of the neoplasm may not be documented if the patient is admitted for a different, unrelated condition, such as trauma or infections.

MEDICARE BAD DEBT

Under existing Medicare and Medicaid law and regulations, state Medicaid programs are required to pay providers for Medicare cost-sharing on behalf of dually eligible Medicare enrollees who are also enrolled in Medicaid. State Medicaid programs are permitted to limit payment for Medicare cost-sharing and providers may recover a portion of unpaid cost-sharing amounts as "bad debt" for Medicare. Before providers can claim these bad debts, the provider must bill the state (or the Medicaid managed care organization) and obtain from the state documentation of completed claims processing and the state's cost-sharing liability. However, some states have not recognized certain provider types under their Medicaid programs. Therefore, CMS proposes to require, for the purposes of determining Medicare cost-sharing obligations, that states' Medicaid programs accept enrollment of all Medicare-enrolled providers and suppliers if they meet all Federal Medicaid enrollment requirement. **We support this proposal, which will facilitate the processing of providers' Medicare bad debt claims in the case that they are not eligible to enroll in states' Medicaid programs.**

More specifically, in the FY 2021 IPPS/LTCH PPS final rule, CMS implemented a "must bill" policy, which requires providers seeking Medicare reimbursement for bad debts associated with dual-eligible patients to first bill the state Medicaid agency for the Medicare cost-sharing amounts and then submit the state's Medicaid remittance advice (RA) to the Medicare administrative contractor (MAC). This change was implemented despite concerns that some state Medicaid programs do not allow LTCHs' enrollment, which prevents them from obtaining a Medicaid RA to present to a MAC.

In this rule, CMS proposes to require state Medicaid programs to enroll Medicare-participating providers for the purpose of determining the state's Medicare cost-sharing obligations. The rule notes that despite this requirement, "some states in the past have inhibited enrollment of certain types of providers or suppliers that are not explicitly included in their State plan."

CMS explains that this problem has affected LTCHs in particular, and thus proposes this fix:

> The State Medicaid agency must allow enrollment of all Medicare-enrolled providers and suppliers for purposes of processing claims to determine Medicare cost-sharing (as defined in section 1905(p)(3) of the Act) if the providers or suppliers meet all Federal Medicaid enrollment requirements, including, but not limited to, all applicable provisions of 42 CFR part 455, subparts B and E. This paragraph (d) applies even if the Medicare-enrolled provider or supplier is of a type not recognized by the State Medicaid Agency.

CMS would allow the states to determine how best to meet this new requirement, and would require compliance by Jan. 1, 2023. The rule explains the agency's expectations that this new requirement should reduce the number of bad debt appeals and related litigation.

Finally, CMS is considering, but did not propose, requiring states to process claims for Medicare cost-sharing even when they do not meet Medicaid coverage and payment rules. **The AHA strongly supports such a requirement and urges its implementation by CMS, which would result in a more comprehensive alignment between state Medicaid enrollment and billing rules and the Medicare must-bill policy.** Further, retroactively applying this change to the greatest extent possible would be of great assistance to the LTCHs affected by this problem, as provider enrollment rules for many Medicaid programs allow a retroactive effective date.

In some cases, the effective date conferred is many months or years prior to the issue date. For example, Tennessee Medicaid issued LTCH provider numbers in February 2008 with an effective date of December 1997. Similarly, some Texas LTCHs received provider numbers in April 2009 that were retroactive to April 2003. In addition, we urge CMS to specify that Medicaid programs must enroll out-of-state Medicare providers and process their Medicare cost-sharing, as it is common for an LTCH located close to a state border to treat patients from a neighboring state. Finally, such Medicaid claims should be exempted from state Medicaid programs' timely billing rules.

QUALITY REPORTING-RELATED PROPOSALS

LTCH Quality Reporting Program (LTCH QRP)

The Affordable Care Act mandated that reporting of quality measures for LTCHs begin no later than FY 2014. Failure to comply with LTCH QRP requirements results in a 2.0 percentage-point reduction to the annual market-basket update. For FY 2020 and FY 2021, CMS requires the reporting of 18 quality measures by LTCHs.

CMS proposes to adopt one measure and adjust the denominator of another for the FY 2023 LTCH QRP, and to begin publicly reporting two LTCH-specific measures. In addition, CMS proposes updating publicly-reported data in light of the COVID-19 public health emergency (PHE) and seeks input on several requests for information (RFIs).

While the AHA appreciates that the proposed measure on COVID-19 vaccination among health care personnel is intended to address an urgently important topic, we do not believe that the measure should be adopted for the FY 2023 LTCH 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 COVID-19 Vaccination among Health Care Personnel (HCP) Measure. This measure would calculate the percentage of HCP eligible to work 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 National Healthcare Safety Network (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 by and for all of our members 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 the vaccines' deployment. 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 thus 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 alike.

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

In its rationale for 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 its vaccines have had a short and at times, unpredictable implementation. The three vaccine products on the market – from Pfizer, Moderna and Johnson & Johnson – are currently only available under the Food and Drug Administration (FDA)'s emergency use authorization. While we are confident in these products' safety and efficacy and the

likelihood that at least one will receive full FDA approval imminently, we find it to be inappropriate to adopt into federal quality reporting programs a measure that assesses the use of a product that has not yet received full federal approval.

Additionally, the measure only excludes patients who do not get a COVID-19 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.

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 that other adopted measures undergo before inclusion in CMS quality reporting programs. The measure was presented to the NQF's Measure Applications Partnership (MAP) as a concept rather than as a measure ready for implementation; in doing so, CMS leadership explained during the MAP meetings that the agency was bringing forward a measure that wasn't "fully fleshed out" in anticipation of its incorporation into rule-writing in 2022.

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 and assesses patients who received at least one vaccine 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 & Johnson vaccine. If the supply chain were disrupted again, health care facilities could be unable to ensure their employees' vaccination status, through no fault of their own. The nation has not yet completed the first wave of complete vaccinations – as of this writing, fewer 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.**

CMS also should consider the measure's potential, unintended consequences. 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 and inpatient psychiatric facilities) do not currently use NHSN to report data for quality reporting programs, so the introduction of this measure would require workflow adjustments 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, publicly reporting performance on this measure might compel facilities to ensure that their employees are vaccinated. Clearly, an employee 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 providers' control. Multiple states already have introduced or passed legislation prohibiting discrimination based on COVID-19 vaccination status; other existing state laws might also prohibit mandatory vaccine policies. In practical terms, this could mean that facilities that are unable to mandate COVID-19 vaccines could be at a systematic performance disadvantage on the measure.

The COVID-19 pandemic is not the last public health emergency this nation will 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, 2021) if not the entire first year; this will allow for time to answer the questions raised above regarding feasibility, validity and the incidence of any unintended consequences.**

Public Reporting for Measures Adopted in FY 2018 Rules. CMS proposes to begin public reporting for two measures: Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay and Ventilator Liberation Rate, beginning with the March 2022 *Care Compare* refresh. The inaugural reporting would be based on data collected in Q3 of 2020 through Q2 of 2021, and then four rolling quarters of data thereafter.

These measures were first adopted in the FY 2018 IPPS/LTCH PPS final rule, and data collection began for patients admitted and discharged on or after July 1, 2018. As we stated in our comments on the FY 2018 rule, we have concerns regarding the specifications of the SBT rule; the overly restrictive timeframe for the measure raises logistical challenges and administrative burden on providers, and might have the unintended consequence of pressuring clinicians to make a judgment without enough information.

In addition, we voiced concerns regarding the multi-component structure of the measure. As specified, the measure is calculated and reported separately for two components: the percentage of patients who were assessed for readiness for the trial

by day 2 of the stay, and the percentage of patients deemed ready who received the trial by day 2. For example LTCHs are required to classify patients as "weaning" or "non-weaning," when in reality patients may not fit squarely into these extremes. Indeed, public comments on the measure demonstrated that the purpose and logistics of reporting both components separately and calculating two different rates are unclear.

In FY 2018, we recommended that particular attention be paid to the adequacy of the risk-adjustment model and patient exclusions for the specifications for this measure. We agree with the goal of removing patients from mechanical ventilation as soon as clinically allowable. However, this goal is far more challenging for patients with more complex diseases or who have more clinical risk factors. Adequate risk adjustment is essential to ensuring that providers do not fare worse on a measure simply because they choose to care for larger proportions of complex patients, such as those with progressive neuromuscular disease, severe neuromuscular injury or who require dialysis.

In the proposed rule, CMS did not provide any updates on performance on these measures since their inception, especially whether our concerns regarding burden, confusion and risk adjustment were realized. We hope that in the final rule, CMS will share their efforts to provide training and guidance on the use of the measures as well as any feedback they have received from providers. If the agency has not yet performed any sort of meta-analysis of these measures yet, we would encourage it to do so.

Request for Information on Health Equity. In light of the Biden administration's efforts to address equity – specifically health equity – the agency requests information on revising several CMS programs to make reporting of health disparities more comprehensive and actionable for providers and patients by basing them on social risk factors and race and ethnicity. 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's focus on addressing disparities in health outcomes by thoughtfully considering how to best leverage data; we agree that 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 face when accessing care; they also can help pinpoint where resources may be deployed to address gaps in access or quality of care as well as provide deeper insights to 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. One way to do this is to consider data collection across the continuum of care. In the FY 2020 proposed rules for the LTCH, IRF, SNF and home health aid 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 U.S. 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 solely 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's 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 is unclear. 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.

Finally, many of CMS's 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 these factors are doubtless vital to assess, the agency – and providers – also need to explore other demographic and social risk factors. These include, but are not limited to, sexual orientation, gender expression, education, literacy, veteran status, disability status, housing, social isolation and community resources.

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 and considering the specific needs and capabilities of post-acute care providers and 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 HITECH Act. In CMS' 2019 RFI that accompanied the Interoperability and Patient Access proposed rule, the agency 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 HIT capabilities in post-acute care is heterogeneous; while some providers have been able to successfully incorporate HIT with higher levels of sophistication, including certified EHR technology (CEHRT), others are using technologies with fewer capabilities for digital exchange. Workforce shortages for HIT professionals and a paucity of resources dedicated to HIT 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 HIT capabilities as well as more opportunities for achievement for those who are well on their way.

Adoption and implementation of HIT systems like CEHRT is not like flipping a switch; it involves painstaking and thoughtful groundwork to establish 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, LTCHs, IRFs, and HHAs 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 – particularly post-acute care providers – and how those expectations differ from the status quo.

The AHA and our members are prepared to collaborate with CMS to build their digital quality measurement enterprise for the future.

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,

Stacey Hughes
Executive Vice President for Government Relations and Public Policy
American Hospital Association