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Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, S.W.  
Room 445-G  
Washington, DC 20201

***RE: CMS-1677-P Medicare Program; Hospital Inpatient Prospective Payment Systems (PPS) for Acute Care Hospitals and the Long-Term Care Hospital PPS and Proposed Policy Changes and FY 2018 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices; Proposed Rule (Vol. 82, No 81), April 28, 2017***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 312 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) 2018 proposed rule for the inpatient and LTCH prospective payment systems (PPS). This letter addresses only the LTCH payment and quality-reporting provisions in the proposed rule. We have submitted separate comments on the agency's proposed changes to the inpatient PPS (IPPS) as well as its request for information related to regulatory burden.

The AHA supports a number of the proposed rule's LTCH's provisions. **In particular, we appreciate the proposal to extend the current pause on full implementation of the 25%**



**Rule for an additional 12 months, beginning October 2017. In addition, as discussed below, we again urge CMS to use its authority to permanently rescind the 25% Rule.** We also support the proposed codification of statutory changes pertaining to the single “cancer LTCH.” However, we have concerns about other provisions in the rule. Specifically, we remain concerned about the agency’s continued application of a duplicative budget neutrality adjustment to the base payment for site-neutral cases, which is producing a systemic and erroneous underpayment of this category of cases. With regard to the proposed new approach for calculating LTCH short-stay outlier cases, while we support the new methodology, we urge CMS not to apply the associated short-stay outlier budget neutrality factor.

**In addition, the AHA recommends that CMS reconsider the adoption of the newly proposed and revised measures for the FY 2020 LTCH Quality Reporting Program (QRP).** The measures should undergo additional testing and investigation so that the specifications reflect actual differences in the quality of care provided rather than compliance with arbitrary processes. **The AHA also believes that the implementation of the standardized patient assessment data elements is too much, too soon, and urges CMS to delay the reporting of the data by at least one year.** The data elements proposed do not have sufficient evidence demonstrating their validity and reliability, and LTCHs would be required to begin collecting the data in less than a year. The burden on providers and difficulty in reconfiguring internal databases, not to mention the significant repercussions on payment associated with the QRP, are too onerous to mandate in such a short time frame.

## **PAYMENT-RELATED PROPOSALS**

### **LTCH 25% RULE RELIEF**

**The AHA applauds CMS’s proposal to implement a 12-month regulatory pause on full implementation of the 25% Rule beginning Oct. 1, 2017.** The agency’s proposal would seamlessly continue beyond Sept. 30 the 25% Rule relief authorized by the 21st Century Cures Act-authorized relief, which runs through Sept. 30. However, our overriding concerns about the 25% Rule remain, as enumerated below, and are the basis for our continued call for CMS to permanently withdraw the policy. **Specifically, we are firmly opposed to the 25% Rule because it would materially reduce payments for care provided to patients who meet the statutory criteria for a full LTCH PPS rate. Further, given the scale of LTCH cuts under site-neutral payment, implementing the 25% Rule payment penalties would unjustifiably exacerbate the instability and strain on the field, which would threaten access for the high-acuity, long-stay patients that require LTCH-level care.**

Implemented by CMS in FY 2006, the 25% Rule reduces LTCH payments to an “IPPS-equivalent” level for patients transferring from a general acute-care hospital to an LTCH and who exceed a particular referral threshold. The referral threshold varies by LTCH type – for

example, rural LTCHs have a more lenient threshold of 50 percent. Currently, the policy is partially implemented at a more lenient level due to multiple congressional interventions that have temporarily blocked full implementation.

**We urge CMS to permanently withdraw the 25% Rule for the following reasons:**

- The 25% Rule is Obsolete. Today's policy landscape for LTCHs is significantly different from that of 2003, when CMS first proposed the 25% Rule. As a result of the following major changes, the 25% Rule is misaligned with the current policy framework for LTCHs:
  - The absence of LTCH PPS payment criteria was regularly cited by CMS as a key rationale for implementing the 25% Rule. However, the Bipartisan Budget Act of 2013 (BiBA) has since required implementation of clinical criteria defining which patients qualify for the LTCH PPS standard rate. As such, this rationale is no longer valid.
  - The scale of the site-neutral cuts is materially reducing aggregate payments to LTCHs – an occurrence unforeseen when the 25% Rule was first implemented. Specifically, even during the phase-in years when the blended rate is still in effect, the policy produced major payment reductions to the site-neutral category: - 23.0 percent for FY 2017 and -14.8 percent for FY 2016. In addition, a further reduction of 22 percent is estimated for FY 2018. Given the magnitude of these cuts and the scope of the policy (*CMS estimates that 42 percent of all LTCH cases in FY 2018 will fall in the site-neutral category*), the field must re-tool operations, with some LTCHs focusing solely on LTCH PPS cases and others re-configuring their operations to create distinct clinical programs for the traditional LTCH and site-neutral patient populations. As noted above, if the 25% Rule payment penalties are implemented at the same time as these substantial cuts and major transformation in the field, it would unjustifiably exacerbate LTCH instability, which would threaten access for the high-acuity, long-stay patients that require LTCH-level care.
  - Alternative payment models, such as bundled payment, also are reducing LTCH utilization due to the setting's high cost. This additional reduction in overall Medicare spending on LTCHs, which also was unanticipated when CMS initially designed the 25% Rule, further heightens our concern about instability in the field.
- The 25% Rule Counters the Statutory Requirements on LTCH PPS Payment. In BiBA, Congress mandated which cases are to be paid an LTCH PPS standard rate, rather than the far lower site-neutral rate. These criteria distinguish patients according to their medical acuity, as indicated by intensive care unit (ICU) and coronary care unit (CCU) use in the prior hospital stay and other metrics. Yet, the 25% Rule would reduce this

mandated payment for some cases that qualify for a standard rate due to the origin of their referral, directly contradicting the payment requirements in BiBA.

- The New Criteria for LTCH PPS Standard Rate Cases Address CMS’s Concerns Regarding LTCH Medical Necessity. The BiBA criteria also directly address another CMS rationale for the 25% Rule that LTCHs provide medically unnecessary care when functioning as “step-down units” for hosting or nearby general acute-care hospitals. However, by identifying the cases that qualify for an LTCH PPS standard rate, the BiBA criteria serve as de facto medical necessity criteria, effectively eliminating the agency’s concern regarding LTCHs serving as step-down units.
- The 25% Rule is Arbitrary. The 25% Rule is non-clinical in nature, targeting patients based on their referral source rather than clinical needs. This is a flawed and arbitrary manner in which to create a policy. As a result, it presents an access barrier for patients who are clinically appropriate for the LTCH setting. In fact, the Medicare Payment Advisory Commission (MedPAC) March 2011 report to Congress described this aspect of the policy as “blunt” and “flawed.”
- CMS has the Authority to Rescind the 25% Rule. The 25% Rule was established through regulation in the FY 2004 LTCH PPS final rule. While multiple congressional bills have temporarily blocked full implementation of the 25% Rule, the resulting statutory language did not mandate implementation of the policy. Thus, CMS has the authority to rescind the policy.

#### **SITE-NEUTRAL CASES ARE BEING UNDERPAID DUE TO DUPLICATIVE BUDGET-NEUTRAL ADJUSTMENTS**

**The AHA appreciates CMS’s decision in the FY 2017 final rule to remove the second budget neutral adjustment (BNA) it had been applying to the high-cost outlier (HCO) portion of site-neutral payments. However, we remain very concerned that the agency continues to apply the duplicative BNA to the non-HCO portion of site-neutral payments.** In its FY 2016 through FY 2018 rulemaking, CMS stated that its rationale for applying a 5.1 percent reduction (hereafter “5.1 percent BNA”) to the site-neutral portion of the blended payment was to avoid any “increase in aggregate LTCH PPS payments.” **However, as we have stated in the past, CMS’s decision to apply two BNAs is yielding a material, unwarranted payment reduction to LTCH site-neutral cases. We strongly urge the agency to withdraw the duplicative BNA.**

Specifically, as discussed in our FYs [2016](#) and [2017](#) comment letters and in other communications with CMS, these site-neutral cases are inappropriately subject to two BNAs:

- The first 5.1 percent BNA is applied when CMS sets the IPPS rates used to calculate the IPPS comparable per diem amount paid to site-neutral cases;<sup>1</sup>
- The second BNA occurs within the LTCH PPS framework, when a second 5.1 percent BNA is applied to the non-HCO portion of the site-neutral payment.

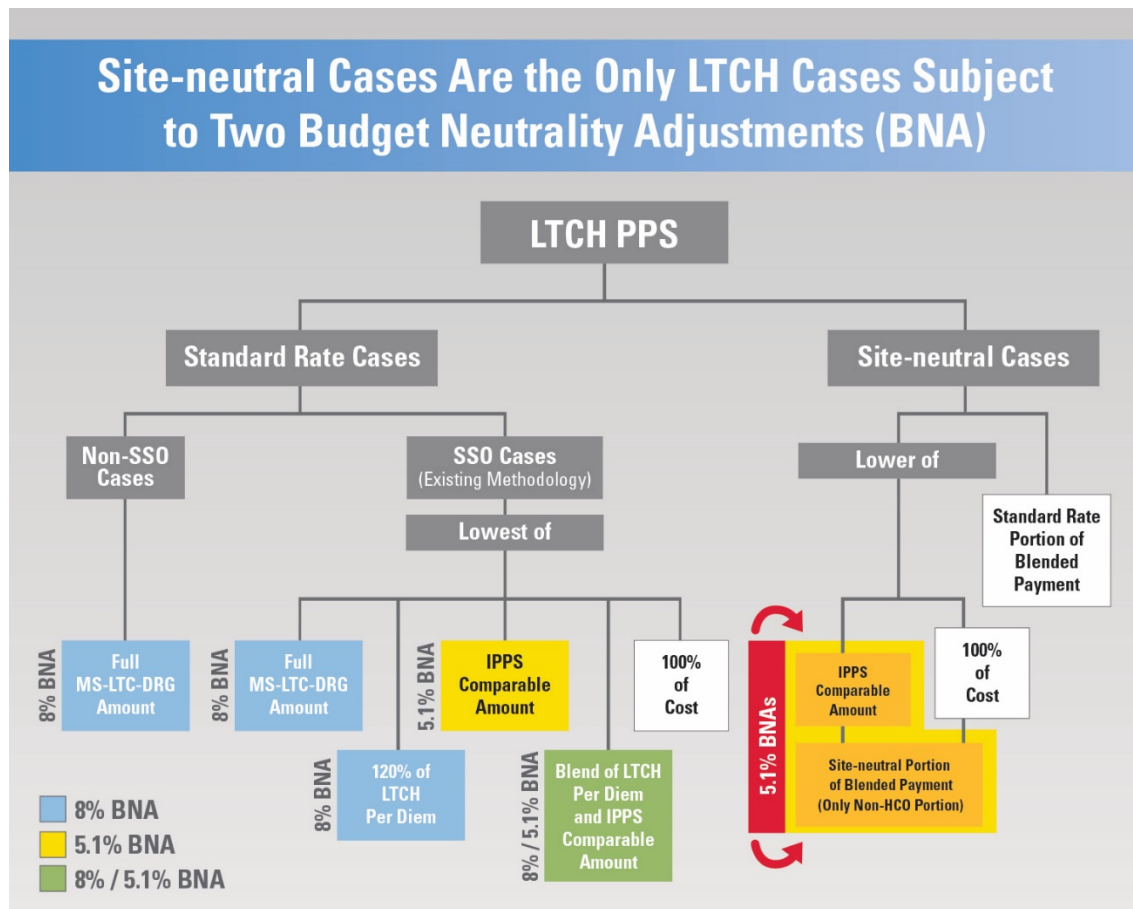
**In addition to its unwarranted duplication, we encourage CMS to consider these other reasons that support withdrawing the second BNA:**

- CMS applies BNAs inconsistently between LTCH standard rate and LTCH site-neutral cases. The chart below outlines and compares BNAs applied to LTCH standard rate and site-neutral cases. Colored cells indicate those claims subject to at least one BNA. When calculating payments for the LTCH PPS standard rate cases (shown on the far left of the chart), only one BNA applies<sup>2</sup>. Similarly, when pricing out the LTCH PPS short-stay outliers (shown at the center of the chart) that are paid either an IPPS comparable amount or cost (similar to what site-neutral cases are being paid), only one BNA applies. However, by contrast, when calculating rates for site-neutral cases paid the IPPS comparable amount, two BNAs apply (shown on the right of the chart).
- CMS did not establish baseline for site-neutral payments. When explaining its site-neutral payment methodology, CMS noted the objective of preventing aggregate LTCH PPS payments from increasing. However, CMS has not provided a “baseline” against which the agency or stakeholders could measure such an increase. Without this baseline, we are not able to gauge whether or by how much the second BNA changes aggregate LTCH payments.
- The second BNA even applies to site-neutral cases paid cost. There is no rationale for CMS to apply any BNA adjustment to site-neutral cases paid cost. Yet, under the currently methodology, even this category of site-neutral cases has a BNA applied at the end of the payment calculation (shown on the far right of the chart).

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<sup>1</sup> The IPPS comparable per diem amount is calculated by dividing the sum of the applicable IPPS operating standardized amount and capital federal rate (adjusted for DRG weighting factors, geographic factors, indirect medical education costs and the costs of serving a disproportionate share of low-income patients) by the geometric mean length of stay for the specific DRG, and multiplying by the covered length of stay. This amount is capped at the full IPPS DRG amount. It is the operating standardized amount and capital federal rate that have already been reduced by 5.1 percent within the IPPS framework.

<sup>2</sup> The LTCH standard federal payment rate, at the implementation of the LTCH PPS, was adjusted downward by a reduction factor of 8 percent to fund the estimated proportion of outlier payments under the LTCH PPS. Although never described in rulemaking by CMS as a “high-cost outlier BNA,” for purposes of this illustration we use the term “8% BNA” to describe it.



- Duplicative BNA does not promote fairness between IPPS and the LTCH PPS. In the FY 2018 IPPS/LTCH proposed rule and other prior rules, CMS states that it believes that using the same fixed-loss amount for site-neutral cases as it does for IPPS cases "will reduce differences between HCO payments for similar cases under the IPPS and site-neutral payment rate cases under the LTCH PPS and promote fairness between the two systems." Yet CMS continues to apply the second, duplicative BNA to the non-HCO portion of the site-neutral payment – this not only causes disparities in the HCO and non-HCO portions of payments between IPPS and the LTCH PPS, but reduces fairness between the two systems. This disparity was also expressed by MedPAC, as noted below.
- MedPAC also views the second BNA as duplicative. In its May 31, 2016 comment letter on the FY 2017 IPPS/LTCH PPS proposed rule, the commission states that "[g]iven that the IPPS standard payment amount is already adjusted to account for HCO payments, CMS' proposal to reduce the site-neutral portion of the LTCH payment by a budget neutrality adjustment of 0.949 is duplicative and exaggerates the disparity in payment rates across provider settings. Given this duplication, CMS should not adjust the site-neutral rate further."

- Duplicative BNA has a Substantial Negative Impact. Using the FY 2015 MedPAR data, we estimate that the second BNA within the LTCH framework reduces site-neutral payments by approximately \$30-\$50 million per year, a substantial amount. This estimate assumes full implementation of site-neutral payment and costs that are similar to IPPS levels versus historical LTCH costs.

## **SHORT-STAY OUTLIER POLICY PROPOSALS**

**The AHA supports CMS's proposal to change the existing short-stay outlier (SSO) policy by replacing the various payment options with a single graduated per diem adjustment. However, we urge CMS not to apply its related proposed one-time permanent budget neutrality factor to the LTCH PPS standard Federal payment rate in FY 2018.** Given the tremendous instability in play with the shift to a dual-rate payment structure, application of a duplicative BNA to the site-neutral payment, and the significant increase in the proposed FY 2018 HCO fixed-loss threshold amount for LTCH standard rate cases, the LTCH field is confronting enormous financial pressure. Furthermore, it is impossible to predict the direction of the field as it struggles to adapt to the dual-rate payment structure, making the actuaries' assumption that there will be a behavioral response of a 10 percent increase in SSO cases arbitrary and inconsistent with the data that CMS examined. The field simply cannot tolerate another large reduction to payments and we urge CMS to do everything in its power to mitigate the instability already being caused.

Overview of SSO Policy and CMS's and MedPAC's Positions. In the FY 2003 LTCH PPS final rule, CMS established a special payment policy for SSO cases – those cases with a covered length of stay that is less than or equal to five-sixths of the geometric mean length of stay (GLOS) for the MS-LTC-DRG in which they are grouped (the SSO threshold). Under the current SSO methodology, Medicare pays an SSO case the lowest of several payment options.

MedPAC and CMS believe that LTCHs have an economic incentive to hold patients until just beyond the SSO threshold since non-SSO cases are generally paid a higher amount. They state that their analyses of lengths-of-stay by MS-LTC-DRG have shown that the frequency of discharges rises sharply immediately after the SSO threshold, thereby partly influencing LTCHs' discharge decisions in addition to clinical considerations.

Proposal to Revise SSO Policy. CMS proposes to revise its SSO policy starting in FY 2018. It would keep the definition of an SSO case unchanged, but pay them a single graduated per diem adjustment: a blend of the "inpatient PPS comparable amount" and 120 percent of the MS-LTC-DRG per diem amount, capped at the full LTCH PPS standard Federal payment rate. The SSO policy only applies to standard rate cases, and not to site-neutral cases. CMS's objective in revising the current policy is to remove any incentive to delay a patient's discharge for financial reasons. CMS states that it found two different impacts of the revised policy on LTCH spending: 1) increased payments to SSO cases of approximately \$145 million purely due to the change in the payment adjustment; and 2) a net decrease of approximately \$43 million in spending due to

an expectation that some non-SSO cases would, in the future, become SSO cases. However, CMS believes that the expected reduction in spending would not offset the increase in spending, and proposes to apply a one-time, permanent budget neutrality factor of 0.9672 to the LTCH PPS standard Federal payment rate to offset this amount, a reduction to the rate of 3.28 percent.

Calculation of SSO Budget-neutrality Factor and Actuarial Assumptions. In order to calculate the SSO budget-neutrality factor, CMS undertook a series of steps which included a behavioral assumption by its actuaries that the proposed SSO methodology would result in a 10 percent reduction in non-SSO cases and a corresponding increase of 10 percent in SSO cases. Specifically, the CMS actuaries observed that in FY 2015, there were 20 percent more discharges occurring just after the SSO threshold than in FY 2002, and that the majority of shifting occurred within three days of the SSO threshold. They then concluded that half of that 20 percent increase (10 percent) would shift to become SSOs.

In order to test the feasibility of the actuaries' assumption, the AHA also examined the distribution of covered days relative to the SSO threshold in the FY 2002 - FY 2016 MedPAR files. While we observed similar patterns described by CMS, we note that there is not only a difference in the proportion of cases within three days of the SSO threshold, but also in the successive three-day period (days four through six after the threshold). As such, although the actuaries concluded that the majority of shifting occurs within three days of the SSO threshold, we note that there continued to be a substantial amount of shifting within six days. Taken together, the percentage difference is as much as 26 percent of total LTCH cases when comparing the FY 2002 to the FY 2015 data and 28 percent when comparing percentages of just the non-SSO cases. Even concentrating on just the three days after the SSO threshold, we question why the actuaries only focused on an even split of the 20 percent observed increase and did not consider alternative scenarios. Replicating CMS's SSO steps, AHA's analysis of the FY 2016 MedPAR data reveals that had the actuaries considered alternative percentages for their behavioral assumptions (e.g., 15 percent or the entire observed 20 percent shifting to SSO cases), the cut necessary to achieve budget neutrality would be lower, and the budget neutrality factor would be higher.

**Considering the arbitrary nature of the actuaries' behavioral assumptions together with the tremendous financial pressure already being faced by the field, the AHA urges CMS to consider not applying the one-time permanent budget neutrality factor to the LTCH PPS standard Federal payment rate in FY 2018.**

#### **REDUCED REGULATORY REQUIREMENTS FOR CERTAIN CO-LOCATED LTCHS**

The AHA supports CMS's proposal to remove the separateness and control requirements for LTCHs and other IPPS-exempt hospitals (such as inpatient psychiatric and rehabilitation hospitals) that are co-located on the campus of another IPPS-exempt hospital. These requirements, which require certain operational practices designed to reduce a co-located hospital's dependence on its host hospital, would still apply when an exempt hospital is co-



located on the campus of an IPPS hospital. We agree that CMS's prior concern – that a de facto “LTCH unit” would allow the hosting general acute-care hospital to receive higher payments by simply transferring the case to the LTCH – has been addressed through other regulatory protections. Specifically, the BiBA criteria established rigorous clinical criteria for an LTCH PPS standard rate, and override the agency's prior concerns regarding a co-located LTCH serving as a "unit."

#### **MAINTAINING ACCESS AND PAYMENTS FOR HIGH-RESOURCE SITE-NEUTRAL CASES**

As Medicare approaches the end of the transition from the single-rate LTCH PPS to the dual-rate version of the payment system, we ask CMS to examine access to care for those site-neutral cases that require specialized high-resource LTCH services. These cases, which include certain severe wound cases, appear to have a cost and average length of stay (ALOS) profile that does not match those of corresponding inpatient PPS MS-DRGs, and thus also appear to be underpaid. As such, while CMS speculated that the resource needs for LTCH site-neutral and inpatient PPS cases would align, it instead appears that some types of site-neutral cases continue to look more like traditional LTCH cases. We believe that site-neutral cases that remain relatively costlier and have longer ALOSs than their inpatient PPS counterparts should be examined to determine if they are being underpaid. We also ask the agency to examine how site-neutral acuity levels and other indicators of resource needs contrast with cases in the comparable inpatient PPS MS-DRGs.

Indeed, Congress has recognized that certain severe wound cases in qualifying LTCHs warrant a waiver from site-neutral payment, and authorized their payment at an LTCH standard rate level on a short-term basis. However, such legislative relief, provided by the Consolidated Appropriations Act of 2016 and 21<sup>st</sup> Century Cures Act, provided a temporary reprieve for a relatively small number of cases. Given the limited nature of this relief, and our growing awareness that certain site-neutral cases may require resources that exceed inpatient-PPS levels, we encourage CMS to undertake a close examination of these cases and consider whether new policy and payment interventions are needed to ensure that these cases have access to high-quality care.

#### **NEW REGULATORY CATEGORY FOR THE “CANCER LTCH”**

We appreciate the changes CMS is proposing to codify the 21st Century Cures Act requirements related to the single LTCH formerly referred to as the “cancer LTCH,” which the BiBA authorized for reasonable cost-based payments commonly referred to as “TEFRA,” instead of LTCH PPS payments. However, with regard to the new regulatory category proposed to separate this hospital from oversight by LTCH regulations, the AHA is concerned that the proposed name, “long-term care neoplastic disease hospitals,” does not align with current terminology and may inadvertently continue to link this hospital to the LTCH category of hospitals. As such, we recommend an alternative descriptor, “hospitals for the treatment of advanced cancer and other diseases.”

## 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 will result in a 2.0 percentage point reduction to an LTCH's annual market basket update. Currently, CMS requires the reporting of eight quality measures by LTCHs and plans to require the reporting of 11 more by FY 2020.

CMS proposes two new measures and the replacement of one measure for the FY 2020 LTCH QRP. The agency also would require LTCHs to collect certain standardized patient assessment data beginning with LTCH admissions on or after April 1, 2018, in order to meet additional requirements mandated by the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014.

**The AHA appreciates that the proposed measures are intended to address significant patient health outcomes; however, all three measures need significant improvement before they would be suitable for use in the LTCH QRP. Furthermore, CMS's proposal to report standardized patient assessment data is too much, too soon, and we believe the data elements require further testing prior to implementation. Therefore, we urge CMS to delay its proposal to report standardized patient assessment data for at least one year.**

### FY 2020 MEASUREMENT PROPOSALS

Changes in Skin Integrity Post-acute Care: Pressure Ulcer/Injury. **The AHA urges CMS not to adopt this measure for the LTCH QRP until it has conducted further testing around the inclusion of unstageable pressure ulcers and deep tissue injuries (DTIs) in the measure calculation.** The LTCH QRP already includes a measure examining the percentage of patients that have new or worsened pressure ulcers. Yet CMS would replace this measure with one that asks LTCHs to capture data on both "stageable" pressure ulcers (i.e., those that can be assigned a numerical score of 1 to 4), and unstageable pressure ulcers, including DTIs, assessing which ones at each stage are unhealed. CMS suggests this change is appropriate because it would capture a fuller range of skin integrity issues. CMS further posits that this measure would help the agency meet its IMPACT Act mandate to implement "interoperable measures" across post-acute care (PAC) settings because this same measure is proposed for other post-acute settings.

**However, the AHA is concerned that the definition of pressure ulcers included in the measure may be too subjective to collect reliable, accurate measure data across LTCHs and other PAC providers. As a result, the measure could provide misleading portrayals of LTCH performance.** As CMS admits in the proposed rule, there are few studies that provide information regarding the incidence of unstageable ulcers in PAC settings. In addition, there is no universally accepted definition for DTIs; in fact, studies have shown that a significant

proportion of DTIs are initially misdiagnosed as stage 1 ulcers or other dermatological diagnoses with similar symptoms that are not intended to be captured by this measure. As a result, the measure may be subject to surveillance bias in which providers have higher rates of DTIs because their surveillance systems are more sensitive to capturing them.

**Furthermore, the AHA is concerned that the measure change would result in artificial distinctions between LTCHs, and these distinctions would be attributed solely to the way injuries are counted, not in the quality of care provided.** CMS believes one of the benefits of implementing this revised measure is that it would increase the variation in measure scores across providers, “thereby improving the ability to discriminate among poor- and high-performing LTCHs.” However, the purpose of changing a measure is not to create performance variation. It is especially troubling when one considers that this increased variation may not stem from differences in quality, but rather from differences in the interpretation of the definitions and differences in the rigor in counting. Measure changes should be rooted in evidence that specifications are inconsistent with current science, or that specifications need further clarity to ensure consistent data collection across providers.

**Thus, the AHA strongly urges CMS to undertake additional testing of the measure to ensure it consistently collects accurate data.** We believe this testing should assess whether the measure is subject to surveillance bias and other unintended consequences that could affect how LTCH performance is reported.

**The AHA also urges CMS to make substantive plans around its promised “additional training opportunities and educational materials” prior to implementation.** CMS is proposing significant changes to the measure data collection approach. Rather than assessing the number of new or worsened pressure ulcers at each stage (as in the current measure), CMS would ask LTCHs to count the number of unhealed pressure ulcers at each stage and subtract the number present upon admission. We believe excluding those pressure ulcers that are present on admission is an appropriate improvement to the measure, but it adds complexity in coding that will be essential to explain to LTCHs. Furthermore, LTCH performance on the revised measure is likely to look quite different from the current measure. Thus, CMS should prepare consumer-facing educational materials explaining why LTCH performance is different.

**Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of LTCH Stay. The AHA urges CMS to further test this measure before implementing it in the LTCH QRP as well as provide flexibility in the screening time frame mandated in the SBT measure.** The proposed process measure assesses facility-level compliance with assessing patients for readiness for a SBT, including a tracheostomy collar or continuous positive airway pressure breathing trial, and performing the trial by the day after admission.

Discontinuing invasive mechanical ventilation as soon as patients are capable of breathing independently can help improve patient respiratory function and reduce the risk of infection. However, CMS provides little evidence to show that requiring the trial by day 2 of the LTCH

stay is the appropriate time frame. In the background on the measure in the proposed rule, CMS cites several studies that merely come to the conclusion that “as soon as possible” is the right time frame. In fact, the most recent study cited by CMS used a five-day time frame.

We are concerned about the feasibility of completing a comprehensive clinical assessment, which is needed to determine whether a patient is stable enough to undergo SBT, by the end of day 2 of the stay. It is common for LTCH admissions to occur in the late afternoon or evening, making the day after admission actually the first day of evaluation with full staffing. This arbitrary and inflexible time frame would increase the administrative burden on providers and might have the unintended consequence of forcing clinicians to make a judgment without sufficient information.

It is concerning that CMS bases its conclusions regarding the time frame and other aspects of the measure (e.g., the exclusion of partial weaning status) based on feedback from its technical expert panel (TEP) and a small pilot test. In the proposed rule as well as in the responses to public comments on the measures, CMS maintains that the TEP believed the measure to be appropriately developed, and therefore no changes to the measure would be made. The TEP used information provided by two former patients and a small pilot test of the data elements involving 10 LTCHs; these test groups represent such a small proportion of LTCHs and their patients that the validity and reliability of the measure are questionable.

**The AHA also is concerned that the multi-component structure of this measure may lead to confusion among providers.** 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 of the stay. A number of subjective definitions are embedded in the calculation of these two rates, including “documentation,” which CMS defines as “explicit physician, registered nurses, or respiratory therapist documentation” — but no indication of what type of documentation or where in the patient’s record this documentation must be inserted. In addition, 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. If finalized, this measure would necessitate the addition of new items to the CARE Data Set; without appropriate training and guidance on how to properly collect data and calculate these measures, little useful information would be produced and it is unlikely care will improve as a result.

**Ventilator Liberation Rate. The AHA urges CMS to further test this measure prior to finalizing it for the LTCH QRP.** Similar to the SBT measure, we are concerned that the small size of the pilot used to inform the development of this measure may not be adequate to conclude the measure is reliable and accurate.

**Furthermore, given that this is an outcome measure, we urge that particular attention be paid to the adequacy of the risk adjustment model and patient exclusions.** We agree with the basic goal that patients should be removed from mechanical ventilation as soon as their clinical condition allows it. But this goal is far more challenging in those 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.

All-cause Unplanned Readmission Measure for 30 Days Post-Discharge from LTCHs. **The AHA is pleased with CMS's proposal to remove this duplicative and confusing measure from the LTCH QRP and supports its removal.** We continue to urge CMS to review the remaining readmission measures used across its PAC quality programs to ensure that they create consistent improvement incentives across the system.

#### **STANDARDIZED PATIENT ASSESSMENT DATA REPORTING**

In addition to requiring standardization and alignment of quality measures, the IMPACT Act also requires the collection of standardized patient assessment data. The reporting of these data is a requirement of the PAC quality reporting programs; as a result, failure to comply with the requirements would result in a 2.0 percentage payment reduction. In an attempt to facilitate data sharing and comparisons across PAC settings, CMS proposes to introduce the required reporting of standardized data elements into each setting's respective assessment tools; for the LTCH setting, this would entail the addition of several new data elements to the CARE Data Set. Specifically, the agency would require LTCHs to collect data on functional status, cognitive function, medical conditions, impairments, and several types of special treatments and services. While PAC providers would fulfill the FY 2019 requirement by reporting data elements already implemented in the various quality reporting programs (namely, those used to calculate the Percent of Residents or Patients with Pressure Ulcers that are New or Worsened, Short Stay), LTCHs would be required to report data based on several new elements starting on April 1, 2018.

**The AHA believes the implementation of these data elements is too much, too soon. We urge CMS to delay the reporting of the data elements by at least one year (i.e., to allow the reporting of elements associated with the Pressure Ulcer measure to fulfill the FY 2019 and 2020 requirements), and to carefully assess whether all of them are necessary to meet the IMPACT Act mandate.**

Validity and Reliability of Elements. Of the proposed 23 data elements, only five are currently reported in the CARE Data Set. The other 18 are used in other post-acute setting tools, mainly the Minimum Data Set (MDS) 3.0 used in skilled nursing facilities (SNFs). CMS purports that the use of these elements in the MDS and the testing in the Post-Acute Care Payment Reform Demonstration (PAC PRD) are sufficient to show that collection of these elements in the LTCH setting is feasible and that the elements will result in valid and reliable data. Unfortunately, the

PAC PRD results were significantly impacted by small sample sizes, and the reliability of many data elements was poor. Thus, it is unwise to rely on results from that project to judge the integrity of the proposed LTCH CARE data elements. In addition, for several of the elements, the precise items CMS proposes to add have not been tested in the PAC PRD or another PAC setting; rather a similar or related item was deemed close enough and thus appropriate for implementation.

Considering that providers are asked to report on these 23 data elements for admissions and discharges beginning in less than a year, and that failure to report would result in a significant decrease in their market basket update, **we believe that CMS has not provided sufficient evidence that these data elements are ready for inclusion in the LTCH QRP.**

Burden on Providers. As mentioned previously, CMS's proposal would add 18 new data elements to the already lengthy CARE Data Set. **Because many of these elements have multiple parts (i.e., a principal element and 2-7 sub-elements or questions), this could result in more than 50 additional tasks for a provider to complete.** While any one task may not take a long time to complete, the addition of all of these elements at once would change a LTCH provider's workflow considerably.

In fact, CMS is currently engaged in multiple contracts to develop several additional standardized patient assessment data elements for future years in PAC QRPs. Unless CMS is planning to significantly reduce the current reporting burdens on PAC providers, it is unrealistic to mandate that providers comply with an exponentially growing list of reporting requirements. We also are concerned about LTCH providers' ability to reconfigure their databases and EHRs by April 2018 to comply with these reporting requirements. For these reasons, we strongly urge CMS to delay implementation of these new data elements. Because the IMPACT Act requires the collection of standardized patient assessment data for fiscal year 2019 and each subsequent year, CMS could consider data already reported in a standardized manner across the various PAC settings to be sufficient for FY 2019 and FY 2020. **CMS proposes that reporting of the elements used to calculate the Pressure Ulcer measure, which has been implemented in all four PAC settings, would satisfy the statutory requirement; the AHA suggests continuing this approach for an additional year to allow for further consideration of the additional data elements.**

### **LTCH QRP PUBLIC REPORTING FOR CY 2018**

CMS proposes to publicly report data in calendar year (CY) 2018 for three assessment-based measures and three claims-based measures. The claims-based measures were those adopted in the FY 2017 IPPS/LTCH final rule, and include:

- Medicare Spending Per Beneficiary,
- Discharge to Community,
- Potentially Preventable 30-Day Post-Discharge Readmissions.

The AHA voiced concern regarding these measures when they were first proposed, some of which were addressed in final rulemaking. Some issues remain, and given that the measures will be publicly reported next year, it is imperative that these measures present an accurate portrayal of provider performance. For this reason, we encourage CMS to continue considering the following recommendations.

Sociodemographic Adjustment. The AHA believes LTCH performance on all three measures may be impacted by sociodemographic factors. We urge CMS to assess each measure for the impact of such factors and incorporate sociodemographic adjustment where necessary.

The evidence continues to mount that sociodemographic factors beyond providers' control – such as the availability of primary care, physical therapy, easy access to medications and appropriate food and other supportive services – influence performance on outcome measures. Most recently, this connection was clearly shown in a report to Congress from the Office of the Assistant Secretary for Planning and Evaluation (ASPE), and in the National Academy of Medicine's (NAM) series of reports on accounting for social risk factors in Medicare programs. Both reports provide evidence-based confirmation of what hospitals and other providers have long known: patients' sociodemographic and other social risk factors matter greatly when trying to assess the quality of health care providers.

Yet, to date, CMS has resisted calls to incorporate sociodemographic adjustment into the quality measurement programs for LTCHs and other PAC providers. Failing to adjust measures for sociodemographic factors when necessary and appropriate can adversely affect patients and worsen health care disparities because the penalties divert resources away from hospitals and other providers treating large proportions of vulnerable patients. It also can mislead and confuse patients, payers and policy makers by shielding them from important community factors that contribute to worse outcomes. Thus, **the AHA urges CMS to incorporate sociodemographic risk adjustment for these outcomes measures.**

Medicare Spending per Beneficiary for LTCHs. The AHA urges CMS to carefully evaluate the MSPB measure's clinical risk adjustment approach. We encourage the agency to work with providers to explore the feasibility of incorporating an adjustment for patient functional status. We believe patient functional status is an important determinant of patient outcomes. CMS could examine whether reliable information on functional status could be collected from claims data. In addition, given that LTCHs and other PAC providers are required by CMS to collect information on functional status as part of patient assessments, CMS should explore whether it is feasible and not overly burdensome to providers to incorporate information from these assessments into the risk model.

Discharge to Community. The AHA urges CMS to carefully assess the reliability and validity of patient discharge codes used to calculate the discharge to community measure. The measure assesses the percentage of Medicare fee-for-service (FFS) patients discharged from LTCHs to home or home health care (i.e., "community discharges") with no unplanned rehospitalizations

or deaths within 31 days of discharge. CMS would identify community discharges using patient discharge status codes recorded on Medicare FFS claims. However, as noted by MedPAC and in other published studies, patient status discharge codes often lack reliability. Given that they are so integral to the calculation of the discharge to community measure, we recommend that CMS test the measure to ensure it provides an accurate portrayal of performance.

Potentially Preventable Readmissions (PPRs). The AHA has long urged that readmission measurement focus on those readmissions that are truly preventable, so we applaud CMS for proposing to remove the duplicative all-cause unplanned readmissions measure from the LTCH QRP. However, we urge continued evaluation of the PPR measure. In particular, the categories and lists of “potentially preventable readmissions” should be based on careful evaluation by clinical experts and detailed testing. We appreciate that a TEP was consulted on the list of categories and codes of readmissions considered “potentially preventable.” However, we strongly encourage CMS to undertake additional empirical testing to ensure there is evidence that the codes actually are associated with the identified categories.

#### **FUTURE CONSIDERATIONS FOR THE LTCH QRP**

In addition to proposing expansions and modifications to the LTCH QRP for proximal program years, CMS also invited public comment on the importance, relevance, appropriateness and applicability of quality measures for future years in the LTCH QRP. We appreciate the opportunity to provide input on these longer term proposals, and hope that CMS incorporates our and others’ comments thoughtfully as the agency further develops the LTCH QRP.

Development of Experience of Care Survey-based Measures. **The AHA has long favored the use of patient experience surveys as tools to help providers improve the engagement and satisfaction of patients and their families. However, the proliferation of questions on such surveys has resulted not only in substantial costs to providers to collect the data, but also a significant burden to patients.** Indeed, many patients have expressed frustration to LTCHs about the length of surveys and the amount of time it takes to complete them. It is critical that surveys include a parsimonious set of questions so that valuable patient time and finite provider resources are used efficiently and effectively.

**We urge that any patient experience of care survey for LTCHs be carefully aligned with other surveys to reduce duplicative collection activities.** A patient’s course of care often crosses multiple care settings and providers within a given time period, and the Consumer Assessment of Providers and Systems (CAHPS) program has surveys for nearly every setting. Indeed, CAHPS includes surveys for physicians, hospitals, nursing homes, dialysis facilities and home health agencies. Patients who receive care in two or more of these settings could receive multiple surveys. Typically, surveys are not distributed until days or weeks after a patient has received their care. This may create confusion about which provider or facility is actually being assessed. A patient may inadvertently attribute a positive or negative experience to the wrong provider.



**The AHA also strongly recommends that CMS explore the development of more economical survey administration approaches for patient experience surveys, such as emailed or web-based surveys.** While we appreciate the value of assessing the patient experience across the care continuum, the use of multiple surveys means more time spent by patients to answer surveys and more resources expended by providers to administer them. Moreover, for the purposes of CMS reporting programs using CAHPS tools, providers are permitted to use only two survey administration modes – mailed surveys and telephone surveys. Mailed surveys are relatively inexpensive to administer, but often suffer from low response rates and significant time lag. Telephonic surveys typically yield a higher response rate and provide more timely results, but are much more expensive to administer.

**Modification of Discharge to Community Measure. The AHA supports the modification to this measure, which would exclude baseline nursing facility residents from the calculation.** As CMS notes, these residents did not live in the community prior to their LTCH stay and thus would not necessarily be expected to return “successfully” to the community following discharge as specified in the measure. This modification would more accurately portray the quality of care provided by LTCHs while controlling for factors outside of the LTCH’s control.

**IMPACT Act Measures on Transfer of Information. The AHA urges CMS to be cautious in its development of these Transfer of Information measures, and only adopt the measures once they have been endorsed by the National Quality Forum (NQF).** The measures under development include “Transfer of Information at Post-Acute Care Admission, Star or Resumption of Care from Other Providers/Settings” and “Transfer of Information at Post-Acute Care Discharge to Other Providers/Settings and End of Care.” We agree that the transfer of information between and among post-acute care settings is vital to ensuring safe and high-quality patient care; however, these measures are still in the early stages of development.

When they were considered by the NQF’s Measure Application Partnership (MAP) this January, the public comment period had closed only a month earlier. The specifications of the measure lacked information on the modes of information transfer and failed to take into account pre-admission screening requirements that are already in place for LTCHs. The MAP voiced concerns that the measures did not ensure that the information being transferred was standardized or provided in a sufficient manner to benefit the patient’s care, and many participants of the MAP worried that this process measure would not yield any useful information that would result in improvements in care or patient outcomes.

As noted in the proposed rule, CMS intends to specify these measures no later than October 1, 2018, and begin data collection on or about April 1, 2019. If these measures cannot pass the NQF endorsement process prior to those dates, **we urge CMS to delay implementation of these measures until they receive endorsement.**

Seema Verma

June 13, 2017

Page 18 of 18

We 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, director of policy, at [rarchuleta@aha.org](mailto:rarchuleta@aha.org), regarding the payment provisions, or Caitlin Gillooley, associate director of policy, at [cgillooley@aha.org](mailto:cgillooley@aha.org), pertaining to the quality-reporting provisions.

Sincerely,

Thomas P. Nickels  
Executive Vice President  
Government Relations and Public Policy