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June 21, 2019

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-1716-P,* Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital PPS and Proposed Policy Changes and FY 2020 Rates; Proposed Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Proposed Requirements for Eligible Hospitals and Critical Access Hospitals: Proposed Rule (Vol. 84, No. 86), May 3, 2019.**

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 241 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) 2020 proposed rule for the inpatient and LTCH prospective payment systems (PPS). This letter focuses on the proposed "50% Rule" provisions, our concerns related to the chronic and substantial underpayment of site-neutral cases, and several issues related patient assessments and quality reporting. We are submitting separate comments on the rule's inpatient PPS proposals.

PAYMENT-RELATED PROPOSALS

SITE-NEUTRAL CASES CONTINUE TO BE UNDERPAID

The implementation of LTCH site-neutral payment, which began in 2015, is bringing a major transformation to the LTCH field. As shown in Chart 1 below, in FY 2020, we anticipate site-neutral cases will be paid 28% less than they otherwise would have.[1] It is clear that the scale of the site-neutral cuts, $1.2 billion since the policy's inception, is materially reducing the overall volume of LTCH cases. Indeed, the AHA and other stakeholders anticipate that the policy will continue to result in not only volume reductions, but further facility closures.

Chart 1: Estimated Impact of LTCH Site-neutral Payments FYs 2016 through 2020

Fiscal Year	Number of Site-neutral Cases (Estimated for FY 2019-2020)	Total Payments if Paid at Full Standard Rate	Total Blended Payments (50% Site-neutral/50% Standard Rate)	Difference*	Percent Difference
2016	53,955	$1.88 B	$1.75 B	-$131 M	-7%
2017	43,163	$1.42 B	$1.03 B	-$382 M	-27%
2018	31,782	$1.04 B	$0.75 B	-$294 M	-28%
2019	24,392	$0.79 B	$0.58 B	-$214 M	-27%
2020	18,721	$0.62 B	$0.45 B	-$174 M	-28%
Total	**-**	**$5.75 B**	**$4.56 B**	**-$1.20 B**	**-21%**

Sources: FY 2016-2018 MedPAR files; FY 2016-2019 final rule and FY 2020 proposed rule CMS public use files for inpatient PPS and LTCH PPS; CMS Provider Specific File (April 2019 update).

* In FY 2016, LTCHs were paid for all discharges (including their site-neutral cases) at the LTCH PPS standard rate until the start of their first cost reporting period beginning after Oct. 1, 2015; this accounts for the smaller difference in FY 2016 between the blended payment and the payment at the full standard rate.

However, these trends continue to be exacerbated by the inappropriate underpayment of site-neutral cases. Specifically, for FY 2020, the AHA projects that only 46% of costs for site-neutral cases, on average, will be covered by Medicare. Yet, CMS continues in its LTCH rulemaking to project that eventually, LTCH site-neutral cases will mirror similar inpatient PPS cases, an expectation that is not supported by the facts. Specifically, the rule cites CMS's continuing expectation that these cases will eventually have a cost and length-of-stay profile that mirrors those of inpatient PPS cases with the same diagnosis-related group (DRG). Contrary to this view, we have seen no movement in that direction since the implementation of site-neutral payment; in

[1] This analysis assumes that site-neutral volume in FY 2019 and 2020 drops by the same percent per year as it did between FY 2016 and 2018 (approximately 23% per year).

fact, as discussed below, the underpayment is worsening. Further, as in prior years, the proposed rule's mention of its projected FY 2020 fiscal impact on site-neutral cases makes no reference to this disturbing underpayment – a critical gap that should be addressed in the final rule.

As detailed below, the AHA continues to ask CMS to respond to the following concerns:

- **Address in detail in the final rule the chronic and substantial underpayment of site-neutral cases and its impact on patients seeking medically necessary LTCH services at the site-neutral level; and**
- **Mitigate the misalignment between the cost of treating LTCH site-neutral cases and their payments by, as recommended by the AHA and Medicare Payment Advisory Commission (MedPAC), eliminating the second budget neutrality adjustment (BNA) that is exacerbating the underpayment of LTCH site-neutral cases.**

Underpayment is Worsening. The magnitude of the chronic underpayment of LTCH site-neutral cases has grown over time. Specifically, as shown in Chart 2, the blended rate payment-to-cost ratio has decreased from 78% in FY 2017 to a projected 73% in FY 2020, while the full site-neutral rate payment-to-cost ratio has decreased from 49% to 46%. Thus far, CMS has failed to discuss its rationale for exacerbating this sustained underpayment, as well as its impact on access to care for patients who meet medical necessity standards for LTCH site-neutral care.

Chart 2: LTCH Site-neutral Cases Payment to Cost Ratios

Fiscal Year	Site-neutral Blended Rate	Full Site-neutral Rate (no blend)
2017	78%	49%
2018	77%	47%
2019	75%	47%
2020	73%	46%

Sources: FY 2017-2018 MedPAR files; FYs 2017-2019 final rules and FY 2020 proposed rule CMS public use files for inpatient PPS and LTCH PPS; CMS Provider Specific File (April 2019 update).

Our analyses refutes CMS's repeated assertion that these cases will eventually mirror comparable[2] inpatient PPS cases. Indeed, our data show that these substantial underpayments are occurring because the acuity level and cost of care for LTCH site-neutral cases persistently remain far above those of comparable inpatient PPS cases. The key driver of the higher cost of treating site-neutral cases is that they have a higher average level of clinical acuity.

Specifically, as shown in Chart 3, we found that 41% of site-neutral cases have five or more complications and comorbidities/major complications and comorbidities (CC/MCC), while only 16% of comparable inpatient PPS cases have five or more CCs or MCCs. Consistent with their high acuity levels, site-neutral cases also have a much higher average length of stay (ALOS), 23 days, than comparable inpatient PPS cases, 3.9 days. The contrast is equally stark when comparing Medicare payment-to-cost ratios: 46% for LTCH site-neutral cases, and 102% for inpatient PPS cases with fewer than three intensive care unit (ICU) days. Average costs per case for these cases were $32,591 and $11,980, respectively. **Collectively, these data show that LTCH site-neutral cases are, on average, sicker and almost three times more costly than inpatient PPS cases with fewer than three ICU days. Yet, the full site-neutral rate covers less than half the cost of care.**

Chart 3: LTCH Site-neutral Cases Compared to Inpatient PPS Cases with Fewer than 3 ICU Days*

	IPPS Cases with <3 ICU Days	LTCH Site-neutral Cases
Number of Cases	6,818,125	30,093
Average Length of Stay	3.9	23.0
% of Cases with 0 CC/MCCs	22%	7%
% of Cases with 1-4 CC/MCCs	62%	52%
% of Cases with 5+ CC/MCCs	16%	41%
Average Cost	$11,980	$32,591
Average Medicare FFS Payment**	$12,167	$14,950
Payment to Cost Ratio	102%	46%

* FY 2018 MedPAR cases with FY 2020 payment parameters.
** Without the site-neutral blend.
Note that for both the inpatient PPS and LTCH scenarios, only providers in the respective FY 2020 proposed rule impact files were selected.

[2] For this discussion, we consider as comparable to LTCH site-neutral cases, inpatient PPS cases with between zero and two ICU days.

Duplicative Budget Neutrality Adjustments Exacerbate Underpayment. Exacerbating the underpayment described above is the fact that the agency continues to inappropriately apply two BNAs to high-cost outlier (HCO) payments when paying site-neutral cases. The first occurs during the establishment of the inpatient PPS rates used as the basis for LTCH site-neutral payment, the second occurs while setting the LTCH payment. **However, the AHA and MedPAC both agree that the second adjustment is duplicative and should not occur.** This is because the inpatient PPS-standard payment amount – the basis for the LTCH site-neutral "IPPS-comparable payments" – already is adjusted to account for HCO budget neutrality. Specifically, in its May 31, 2016 comment letter on the FY 2017 inpatient PPS/LTCH PPS proposed rule, MedPAC 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."*

The AHA's concerns regarding the duplicative BNA were explained in detail in our comment letters on the FYs 2017 and 2018 proposed rules for the LTCH PPS, as well as during in-person meetings and calls with CMS staff. In partial recognition of these concerns, CMS, in FY 2017, stopped applying the second BNA to the high-cost outlier portion of LTCH site-neutral payments. However, it still applies it to base payment. **We strongly urge CMS to re-examine and withdraw the second BNA applied to base payments.**

LTCH 50% RULE

The Bipartisan Budget Act of 2013 requires that, beginning in FY 2020, LTCHs must focus on treating patients that are paid a standard LTCH PPS rate, in order to maintain payments under the LTCH PPS. Specifically, more than half of an LTCH's discharges per year would need to be paid a standard LTCH PPS rate, instead of an LTCH site-neutral rate, to avoid a significant payment cut. The rule proposes that for cost reporting periods beginning on or after Oct. 1, 2019, any LTCH with 50% or fewer discharges paid a standard rate would have a payment penalty applied to all discharges in a subsequent cost reporting period. The rule also proposes a process for reinstating LTCHs to 50% Rule compliance, as well as a special probationary reinstatement process. The agency notes its plans to use subregulatory guidance to fully implement this policy.

CMS asked stakeholders for feedback on this proposal, including whether it should align the 50% Rule reinstatement process with that used to reinstate LTCHs following non-compliance with the policy requiring LTCHs to maintain an ALOS of at least 25 days. **The AHA appreciates CMS proposing a 50% Rule methodology that aligns with**

the statute. We have several recommendations to streamline and simplify the process for both CMS and providers:

- CMS should require its contractors to examine other data sources, including inpatient PPS matching claims, when calculating 50% Rule compliance. Since LTCHs have no control over the timing of when information on the prior hospital stay becomes available, and prior ICU days help determine an LTCH's 50% Rule compliance status, contractors should attempt to match the related inpatient PPS and LTCH claims as part of their policy implementation process. This approach would mitigate the frequent LTCH challenges associated with delayed access to data confirming the patient's ICU days during the prior hospital stay, which determine whether the case will fall in the standard rate versus site-neutral category.

- As proposed, the 50% Rule compliance review process can span many years. Specifically, noncompliance during a particular cost reporting period can stretch to include approximately four years of interactions between Medicare and the LTCH if the special probationary process and then retroactive cost settlement (up to 18 months) are triggered. We support truncating this process by aligning the compliance assessment, notification and reinstatement protocols with those used for the LTCH ALOS compliance reinstatement policy. LTCH stakeholders indicate that using this more streamlined process would reduce the 50% Rule compliance review process to approximately two years.

  Specifically, LTCHs that lose compliance with the 25+-day ALOS requirement receive an additional period of time to come back into compliance, which is known as a "cure period." The cure period allows the noncompliant LTCH to demonstrate it has restored compliance during at least five out the immediately preceding six months. This process allows CMS to maintain the policy standard without relying on an overly lengthy and complex process. It also allows providers to avoid the burden and instability associated with cost report settlement. In addition, the cure period is known to the LTCH field, which is already facing a major transformation and has limited bandwidth to absorb additional complex requirements. Further, streamlining the 50% Rule and ALOS compliance processes would be beneficial for both CMS and providers.

- 50% Rule compliance should be calculated on a per-organization basis, rather than per-individual site, since CMS and its contractors treat multi-campus providers under one provider number.

- The final rule should confirm that LTCHs retain their status as inpatient PPS-excluded hospitals during the 50% Rule compliance reinstatement process. This clarification should explicitly state that any 50% Rule penalty is an adjustment to an LTCH payment that does not represent any change in LTCH status.

- In alignment with statute, the final rule should affirm that LTCHs can appeal determinations of 50% Rule noncompliance.

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 the LTCH's annual market-basket update. Currently, CMS requires LTCHs to report 18 quality measures.

In this proposed rule, CMS proposes to add two measures to the FY 2022 LTCH QRP. In addition, CMS would require LTCH s to collect certain standardized patient assessment data beginning with LTCH admissions on or after Oct. 1, 2020 to meet additional requirements of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014.

While the AHA appreciates that the proposed measures are intended to address important aspects of care transitions and have undergone significant improvements over the past few years, we continue to encourage CMS to only adopt measures that are endorsed by the National Quality Forum (NQF). Furthermore, we urge CMS to reconsider its proposal to adopt all at one time the dozens of standardized patient assessment data and determine whether it is necessary or useful for LTCHs to collect all of the proposed data.

FY 2022 MEASUREMENT PROPOSALS

Transfer of Health Information to the Provider – Post-Acute Care (PAC). CMS proposes to add this process measure to the FY 2022 LTCH QRP. The measure assesses the proportion of patient stays with a discharge assessment indicating that a current reconciled medication list was given to the subsequent provider at the time of discharge or transfer from the patient's current PAC setting. The same measure was proposed for inclusion in the skilled nursing facility (SNF) and inpatient rehabilitation facility (IRF) QRPs as well. If finalized, IRFs, SNFs, and LTCHs would be required to submit measure data beginning with Oct. 1, 2020 admissions and discharges.

The AHA agrees with CMS that sharing patient information in a timely manner is vital to smooth transitions of care and better patient outcomes. The measure also fulfills an IMPACT Act quality measure domain requirement, and its specifications have

undergone significant improvements since it was first introduced. **However, we urge that the measure receive NQF endorsement before it is adopted in the LTCH QRP.** We acknowledge NQF endorsement is not required of LTCH QRP measures, and appreciate the agency's intent to "submit the proposed measure to NQF for consideration of endorsement when feasible." Nevertheless, CMS should adopt only measures that have undergone this robust evaluation process and received endorsement. The multi-stakeholder NQF endorsement process determines whether measures meet basic criteria to indicate suitability for use in QRPs and may highlight areas where the measure's specifications may be tweaked to improve reliability, accuracy and feasibility.

In addition, we question the ability of this process measure to meaningfully improve care. In this case, high performance would mean only that providers are sending a reconciled medication list – not that the subsequent provider received it, or that the list was accurate, or that patients experienced fewer adverse events. As a result, the measure could become a "check-the-box" proxy measure for high-quality care. With that in mind, we encourage CMS to monitor the outcomes of interest that are associated with this measure (e.g., adverse drug events) to determine if this measure is having any effect.

Transfer of Health Information to the Patient – PAC. CMS proposes to add this process measure to the FY 2022 LTCH QRP. The measure assesses the proportion of patient stays with a discharge assessment indicating that a current reconciled medication list was given to the patient, family, or caregiver at the time of discharge to the home; the same measure was proposed for inclusion in the SNF and IRF QRPs as well. If finalized, IRFs, SNFs and LTCHs would be required to submit measure data beginning with Oct. 1, 2020 admissions and discharges.

We reiterate our recommendation above that **CMS wait until this measure receives NQF endorsement before adopting it into the LTCH QRP.** In addition, we also urge CMS to use the field's experience with transferring information to patients and reporting on this measure to disseminate best practices about how to best convey the medication list. This includes any formats and/or informational elements that are particularly helpful for patients and families. In order to achieve the goals of this measure, merely printing off a list or transmitting it through an electronic health record would not ensure that the patient has any more ability to prevent adverse events.

Update to the Discharge to Community Measure. CMS proposes to exclude baseline nursing facility residents – patients who are admitted to the LTCH following a long-term nursing facility stay with no intervening community discharge between the nursing facility stay and hospitalization prior to LTCH admission – from calculation of the Discharge to Community measure. Based on public comment suggesting that these patients are far less likely to return to the community, CMS found that the rates of

discharge to the community were significantly lower for baseline nursing facility residents compared with patients who did not come from a nursing facility, suggesting that including these patients in measure calculations unfairly skews performance. **The AHA appreciates CMS's willingness to consider feedback on this measure's calculation and supports the proposed change to this measure.**

STANDARDIZED PATIENT ASSESSMENT DATA ELEMENT (SPADE) REPORTING

In addition to requiring the adoption of standardized and interoperable quality measures, the IMPACT Act also requires that, for FY 2019 and each subsequent year, PAC providers must report SPADEs. The reporting of these data is required in the PAC QRPs, and as a result, failure to comply with the requirements results in a payment reduction. The SPADEs must satisfy five domains: functional status, cognitive function, special services, medical conditions and comorbidities, and impairments.

In the FY 2018 LTCH PPS proposed rule, CMS proposed to adopt SPADEs that would satisfy all five domains. However, the agency did not finalize most of these proposals in response to the concerns raised by AHA and others regarding the speed and magnitude of the additions to already lengthy patient assessment instruments. Stakeholders also were concerned that the data elements had not been tested for use in each specific PAC setting. That is, CMS proposed to adopt for all four settings data elements that were only tested in one PAC setting without determining whether those elements provided reliable and valid data in other settings. Instead, CMS finalized the adoption of SPADEs in just two categories (functional status and medical conditions and comorbidities) based on data elements already finalized for adoption in the various instruments.

In this year's proposed rule, CMS asserts that LTCHs have had sufficient time to familiarize themselves with other new reporting requirements adopted under the IMPACT Act. In addition, CMS cites the results of a recent National Beta Test of the proposed data elements conducted by its contractors to suggest that SPADEs are now tested adequately. Based on these developments, CMS proposes to add 25 SPADEs to the LTCH CARE Data System (LCDS) – including the same SPADEs as proposed for the IRF and SNF patient assessment tools as well as six additional items that were previously adopted in the other PAC settings' tools – which providers would be required to report beginning Oct. 1, 2020. Many of these SPADEs would satisfy the domains required by the IMPACT Act; several more would be added under a newly proposed domain on social determinants of health (SDOH).

We believe that CMS's proposal to add 25 new SPADEs – associated with potentially more than 60 new data elements to complete, depending on the patient – to the LCDS at one time would add administrative burden that far outweighs the benefit to patients or LTCHs. Furthermore, the proposal fails to

fulfill the goals of the IMPACT Act. As a result, the AHA strongly urges CMS to finalize only a subset of the proposed SPADEs for adoption and pursue a gradual rollout of new requirements.

Burden on Providers. As mentioned previously, CMS's proposal would add 25 new data elements to the already lengthy LCDS. Because many of these elements have multiple parts (i.e., a principal element and two to 12 subelements or questions), this could result in more than 60 additional tasks for a provider to complete. According to data provided in the proposed rule, the addition of all of these elements at once would add nearly 20 minutes to the assessment (7.8 minutes upon admission and 11.1 minutes at discharge). CMS estimates the time required to complete information collection for the current version of LCDS (LCDS 4.0) – including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection – is on average 53.5 minutes per patient;[3] the proposed additional SPADEs would increase this time by approximately 37%. With approximately 116,000 LTCH stays per year (as of 2017[4]), the additional patient assessment tasks would result in **nearly 39,000 more hours of time spent on patient assessments.**

This additional data collection burden might be appropriate if the data were necessary to meet IMPACT Act requirements, or had such inherent value to patient care that the time spent collecting the data was "worth it." Yet, the IMPACT Act does not require the magnitude of SPADEs that CMS is proposing, only that the agency adopt SPADEs that meet the various domains specified under the law. Furthermore, as detailed below, CMS's proposals would ask LTCHs to collect and report several data elements whose relevance and value to care is dubious at best. Neither the passage of time since the FY 2018 rules nor CMS's efforts to reduce some burdens in the LTCH QRP in the FY 2019 rulemaking process have created a sufficient ability to shoulder the burden that would suddenly be placed upon LTCHs on Oct. 1, 2020. Even more troubling, CMS requests feedback on the development of *even more* SPADEs in this very proposed rule. Unless the agency 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.

Relevance and Reliability of Data Elements to LTCHs. **The AHA is concerned that many of the proposed SPADEs appear to occur for LTCH or PAC patients**

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[3] Department of Health and Human Services Centers for Medicare & Medicaid Services Office of Management and Budget Paperwork Reduction Act Clearance Package, Supporting Statement – Part A, Revisions to the LTCH CARE Data Set for the Collection of Data Pertaining to Long-term Care Hospital Quality Reporting Program. Accessible: https://www.reginfo.gov/public/do/DownloadDocument?objectID=83146600.

[4] Medicare Payment Advisory Commission *Report to Congress*, March 2019, Ch. 11, "Long-term Care Hospital Services." Accessible: http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch11_sec.pdf?sfvrsn=0.

infrequently, thereby limiting the utility of the data collected. The National Beta Test's results show that many of the SPADEs in the Special Services, Treatments and Interventions domain applied to less than 3% of PAC patients; in certain cases, 0% of PAC patients noted that SPADE. For example:

- Respiratory Treatment; Invasive Mechanical Ventilator: 0% of all PAC patients had invasive mechanical ventilation noted.
- Transfusions: 0% of all PAC patients had transfusion noted.
- Cancer Treatment: Chemotherapy: 1% of all PAC patients had chemotherapy noted.
- Cancer Treatment: Radiation: 3% of all PAC patients had radiation noted.
- Respiratory Treatment: Suctioning: 1% of all PAC patients had suctioning noted.
- Respiratory Treatment: Tracheostomy Care: 1% of all PAC patients had tracheostomy care noted.
- Respiratory Treatment: Non-invasive Mechanical Ventilator: 5% of all PAC patients had non-invasive mechanical ventilation noted.
- Dialysis: 5% of all PAC patients had dialysis noted.
- Nutritional Approach: Parenteral/IV feeding: 1% of PAC patients had parenteral/IV feeding noted.
- Nutritional Approach: Feeding Tube: 2% of PAC patients had feeding tube noted.
- Hearing: 1% of PAC patients demonstrated severely impaired hearing.
- Vision: 3% of IRF patients demonstrated severely impaired vision.

In addition, CMS proposes to add six elements that were previously finalized in the other PAC settings. These elements are part of Section GG, a section that captures information related to patient functional abilities and goals that was added to the various patient assessment tools for collection beginning in 2016. When Section GG was implemented across the various PAC settings, these six elements – car transfer, walking 10 feet on uneven surfaces, one-step (curb), four steps, 12 steps, and picking up object – were not finalized for LTCHs.

Presumably, these items were not finalized for LTCHs because their patients are critically ill and usually transferred from a hospital ICU; walking around is usually not a high priority, and for many LTCH patients, it is impossible. In fact, over a decade ago, CMS developed and tested these same items in the Post-Acute Care Payment Reform Demonstration (PAC-PRD).Reviewers noted that LTCH patients had the most frequent use of codes indicating that these activities were not completed by LTCH patients, which is consistent with the acuity of LTCH patients. For all six proposed elements, patients did not perform an activity or data was missing (usually because patients had more urgent medical needs) more than 90% of the time.[5]

[5] Analysis of Crosscutting Medicare Functional Status Quality Metrics Using the Continuity and Assessment Record and Evaluation (CARE) Item Set, Final Report. November 2012. Accessed: https://aspe.hhs.gov/system/files/pdf/138711/rpt_crossmedi.pdf.

We recommend CMS not finalize the adoption of these six elements in the LCDS, as the process for assessing patients for these functional activities is burdensome to perform and will not provide useful information.

The AHA questions why CMS would force overworked patient care staff to ask questions to which CMS already knows the answer, which –according to assessor feedback gleaned from the National Beta Test – often entails consulting multiple information sources to determine whether patients were receiving certain treatments. Assessor feedback suggests that this information can be found in other data sources, like claims, or is already noted by patient care staff, and thus does not need to be collected during the assessment process.

CMS cites the results of the National Beta Test to suggest that the SPADEs are now adequately tested and appropriate for adoption. However, for multiple proposed items, the results point to the opposite conclusion. In addition to the low frequency of many SPADEs, statistical performance and assessor feedback gathered during the National Beta Test show that some elements are not appropriate for use in patient assessments, including:

- Intravenous Medications (Antibiotics, Anticoagulation, Vasoactive Medications, Other): Reliability only fair to good, and poor for the Anticoagulation subelement.
- Patient Health Questionnaire 2-9: burdensome for staff and patients, wording difficult to understand
- High-Risk Drug Classes: adverse drug events are not limited to high-risk drugs, so question has limited utility; in addition, finding the indications for drugs in the class is highly burdensome.

The IMPACT Act does not mandate that *only* standardized patient assessment data be collected and quality measures reported; each PAC setting differs in the type of care it provides and the characteristics of patients and residents it cares for. **Considering the shortfalls of these SPADEs, the AHA recommends that CMS fulfill its statutory requirements to adopt SPADEs as mandated by the IMPACT Act by adopting only those elements that demonstrate high statistical reliability and utility for all PAC providers.**

SDOH Data Elements*.* In addition to the five domains mandated by the IMPACT Act, CMS proposes to add a new domain related to SDOH, also known as social risk factors. Each of the data elements proposed was identified in the 2016 National Academies of Sciences, Engineering, and Medicine (NASEM) report “Accounting for Social Risk Factors in Medicare Payment: Identifying Social Risk Factors,” which was commissioned by the Department of Health and Human Services Assistant Secretary for Planning and Evaluation. In this report, NASEM identified these factors as having impact on care use, cost and outcomes for Medicare beneficiaries.

The AHA does not oppose the concept of collecting SDOH data elements. If implemented appropriately, such data could be useful in identifying and addressing health care disparities, as well as refining the risk adjustment of outcome measures. **However, we urge CMS not to finalize the proposed policy until it can address several important issues** around the potential future uses of these elements and the requirements around data collection for certain elements.

First, the IMAPCT Act requires CMS to assess "appropriate adjustments to quality measures, resource measures and other measures, and to assess and implement appropriate adjustment to payment under Medicare…after taking into account studies conducted by ASPE on social risk factors." CMS does not state explicitly in the rule whether it anticipates the SDOH SPADEs will be used in adjusting measures, but we believe the IMPACT Act's requirements make it likely the SPADEs will be considered for use in future adjustments. Going forward, **we urge CMS to be circumspect and transparent in its approaches to incorporating the data elements proposed in payment and quality adjustments. In part, this can be accomplished using processes like "dry runs" of any adjustments, and by collecting stakeholder feedback before implementing any adjustments.** It is important to understand and account for the impacts social risk factors have on patient outcomes and costs without unfairly penalizing providers who care for vulnerable populations or excusing poor care by pointing to patient characteristics.

Second, CMS notes that, if finalized, LTCHs would need to submit only data on the Race and Ethnicity SPADEs with respect to admission and would not need to collect and report again at discharge, as it is unlikely that patient status for these elements will change. We believe that a patient's preferred language, need for an interpreter, health literacy, access to transportation, and social isolation also are unlikely to change between admission and discharge; thus, **we urge CMS to require collection of all SDOH SPADEs with respect to admission only.**

Finally, we are unsure that the response options under the Race data element are the right ones. From our research, it appears that some of these 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 (OMB). In addition, these select categories are not consistent with the recommendations made in the 2009 Institute of Medicine (IOM) report on Standardized Collection of Data on Race, Ethnicity, and Language, even though CMS cites this report in explaining its proposals.

Specifically, the IOM report recommends using the broader OMB race categories (Black or African American, White, Asian, American Indian or Alaska Native, Native Hawaiian or Other Pacific Islander, and some other race) and granular ethnicities chosen from a national standard set that can be "rolled up" into those categories, and ideally the

granular options would be tailored to the local market. In addition, the report recommends that each set of categories should include an "Other, please specify: ___" option to allow individuals to self-identify. It is unclear how CMS chose the 14 response options under the Race data element and the five options under the ethnicity element, as they do not match the minimum categories used by OMB or the process for capturing granular data recommended in the IOM report.

We worry that these response options will add to the confusion that may already exist for patients about what terms like "race" and "ethnicity" mean for the purposes of health care data collection. In fact, the IOM report states that "[a] lack of standardization of race, ethnicity, and language categories has been raised as one obstacle to achieving more widespread collection and utilization of these data." **CMS should confer directly with experts on this issue to ensure patient assessments are collecting the right data in the right way before these SDOH SPADEs are finalized.**

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 regarding the payment provisions; or Caitlin Gillooley, senior associate director of policy, at cgillooley@aha.org pertaining to the quality-reporting provisions.

Sincerely,

/s/

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