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Advancing Health in America

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June 17, 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-1710-P, Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2020 and Updates to the IRF Quality Reporting Program***

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 1,000 inpatient rehabilitation facilities (IRFs), and our clinician partners – including more than 270,000 affiliated physicians, 2 million nurses and other caregivers – and the 43,000 health care leaders who belong to our professional membership groups, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) fiscal year (FY) 2020 proposed rule for the IRF prospective payment system (PPS). Our comments focus on elements of the FY 2020 case-mix system reforms finalized in last year's rulemaking, as well proposed changes to quality outcomes reporting and patient assessments.

Beginning Oct. 1, 2019, the current patient assessment process and case-mix systems of the IRF PPS will be materially altered. **The AHA generally supports the reforms to update this payment system. However, we are concerned about the substantial redistribution of cases under the payment model proposed for FY 2020. In addition, we remain concerned that these new policies are, in part, based on unreliable data and that the proposed rule lacks adequate detail and transparency.** We also are concerned that the proposed rule lacks the patient-level and cost data needed to replicate the model for the purpose of evaluating its impact to consider whether alternatives would be warranted. **These issues deserve further discussion and transparency in the final rule to allow the field to best prepare for the changes and serve their patients.**

## PROPOSALS RELATED TO THE FY 2020 CASE-MIX SYSTEM REFORMS

The AHA is concerned with the case redistribution under the updated IRF payment units, known as case mix groups (CMGs), the proposed weighted motor score methodology and the proposed rule's shortcomings related to transparency and data reliability.

Specifically, effective Oct. 1, 2019, CMS will implement a reformed IRF case-mix system based on recalibrated CMGs. This is the first significant reform of the CMGs since the IRF PPS was implemented in 2002. It increases the number of CMGs (from 92 to 97) and redistributes cases across them. The updated payment model is based on data from FYs 2017 and 2018, which include new quality indicators from Section GG of the IRF-patient assessment instrument (PAI) that was implemented on Oct. 1, 2016. In FYs 2017 and 2018, these new data were collected concurrently with the prior, similar FIM™ items, which are used for payment setting through September 2019.

Concerns Related to Redistribution of Cases Across the Recalibrated CMGs. While the CMG reforms are budget neutral relative to the current system, they would cause significant redistribution for the field as a whole, which is a concern given the magnitude of the shifts. As demonstrated in chart below, for stroke cases, the number of CMGs would be reduced from 10 to seven. The 218 higher-acuity cases in the eliminated CMGs 108, 109 and 110, which account for almost two thirds of inpatient rehabilitation provider cases, would be redistributed across the compressed set of seven CMGs. Indeed, many stroke cases would be shifted from the three eliminated CMGs to CMGs for lower levels of medical complexity. **The number of cases in CMG 101 increased, for example, by 1200%**. This is but one instance of a material shift and compression in grouping and payment. A shift of this magnitude warrants an explanation in the proposed rule, although one was not provided. In addition, the data files issued with the rule indicate substantial impact at the provider level, ranging from a 17 percent decrease to a 27 percent increase in payments under the proposed CMGs, but the rule also lacks a discussion of how this shift would affect provider operations and, more importantly, patient access.

**Redistribution of Stroke Cases under the Proposed FY 2020 CMGs**

| | | Proposed FY 2020 CMGs | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| FY 2019 CMGs | | 0101 | 0102 | 0103 | 0104 | 0105 | 0106 | 0107 | Total |
| | 0101 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 2 |
| | 0102 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 4 |
| | 0103 | 2 | 0 | 1 | 0 | 0 | 0 | 0 | 3 |
| | 0104 | 11 | 14 | 5 | 0 | 0 | 0 | 0 | 30 |
| | 0105 | 2 | 6 | 6 | 2 | 1 | 0 | 0 | 17 |
| | 0106 | 1 | 16 | 14 | 2 | 0 | 0 | 0 | 33 |
| | 0107 | 2 | 7 | 19 | 8 | 3 | 0 | 0 | 39 |
| | 0108 | 0 | 2 | 4 | 5 | 17 | 15 | 0 | 43 |
| | 0109 | 0 | 1 | 12 | 5 | 9 | 0 | 4 | 31 |
| | 0110 | 0 | 2 | 4 | 16 | 29 | 0 | 93 | 144 |
| | Total | 24 | 48 | 65 | 38 | 59 | 15 | 97 | 346 |

Source: Kindred data on stroke patients, January 2018 through April 2019

**We urge CMS to share its policy rationale for these and other substantial redistributions in the final rule. Absent a substantial justification for these shifts, the agency should implement an approach to mitigate these redistributions. Further, we call on CMS to explain its projections regarding the impact of these redistributions on patients' access to care.**

Concerns Related to the Proposed Weighted Motor Score. While the FY 2019 final rule implemented an *unweighted* motor score, the FY 2020 proposed rule changes this position by recommending a *weighted* motor score. That is, it would weight certain items more than others when computing the score. CMS's rationale for the weighted approach is that it "slightly improves" the ability of the IRF PPS to predict patient costs. Unfortunately, it also would result in unexplained and substantial shifts in values for important motor items, as described further below. In addition, both the proposed rule and associated technical report lack a full explanation of the agency's design and weighting rationale and criteria. The rule also fails to discuss the potential reduction of access to care for patients needing treatment for motor skills that would significantly drop in value under the proposed weighted methodology, which would therefore result in reduced payment.

The chart below, created by Kindred, lists the motor score items with current and proposed weights and illustrates our concerns with the significant shifts in weights from those in the current motor score methodology as compared with the proposed approach. In particular, we have questions about the items experiencing the most notable shifts, such as the significant weighting increases for the eating, toileting and bladder continence items. We also note the significant decreases in value for the mobility items, such as for the walking and chair/bed-to-chair transfer items. Unfortunately, the rule does not discuss these shifts, either at the item level or with regard to the overall shift in weight value from mobility to self-care items.

**Motor Score Items with FY 2019 and Proposed FY 2020 Weights**

| Motor Score Items | FY 2019 Weight | Proposed FY 2020 Weight |
|---|---|---|
| GG0130A1 - Eating | 0.6 | 2.7 |
| GG0130B1 - Oral hygiene | | 0.3 |
| GG0130C1 - Toileting hygiene | 1.2 | 2 |
| GG0130E1 - Shower bathe self | 0.9 | 0.7 |
| GG0130F1 - Upper-body dressing | 0.2 | 0.5 |
| GG0130G1 - Lower-body dressing | 1.4 | 1 |
| GG0130H1 - Putting on/taking off footwear | | 1 |
| GG0170B1 - Sit to lying | | 0.1 |
| GG0170C1 - Lying to sitting on side of bed | | 0.1 |
| GG0170D1 - Sit to stand | | 1.1 |
| GG0170E1 - Chair/bed-to-chair transfer | 2.2 | 1.1 |
| GG0170F1 - Toilet transfer | 1.4 | 1.6 |
| GG0170I1 - Walk 10 feet | 1.6 | 0.8 |
| GG0170J1 - Walk 50 feet with two turns | 1.6 | 0.8 |
| GG0170K1 - Walk 150 feet | 1.6 | 0.8 |
| GG0170M1 - One-step curb | 1.6 | 1.4 |
| H0350 - Bladder continence | 0.5 | 1.3 |
| H0400 - Bowel continence | 0.2 | 0.7 |

**We are concerned that these shifts could inadvertently understate patients' needs and, ultimately, lead to underpayment of medically necessary services for patients receiving treatment for mobility-related needs. Given these concerns, we ask the agency to postpone the use of a weighted motor score and, instead, use the unweighted approach in FY 2020, as finalized in last year's rulemaking.** Using an unweighted motor score until data can be collected under the new case-mix system mirrors the staged implementation approach CMS used when the IRF PPS was implemented in 2002. In addition, this extra time would provide CMS with another opportunity to ensure that its weighted motor score criteria and design features are applied consistently and communicated in a comprehensive and transparent manner to stakeholders. Continued use of the FY 2019 weights also warrants examination and consideration as an option for FY 2020.

To help explain our concerns about the lack of transparency with the agency's rationale for a weighted motor score, we share a sampling of the motor score-related concerns raised by UDSMR™:

- Although the individual elements in the current and proposed motor score were initially tested for reliability and validity, the resulting motor score has not been tested for reliability and validity. As such, CMS has not demonstrated that the motor score is capable of measuring what it is supposed to measure or is predictive, on its own, of cost.
- CMS has not explained why both the proposed unweighted (last year) and weighted motor scores (this year) show little to no correlation with the weighted motor score currently in use. In addition, the substantial shift in the resulting patient-severity levels relative to those produced by the current system, which were found reliable and valid, has not been explained.
- CMS removed the "roll left and right" functional item from the proposed motor score due to being highly correlated with other items; however, additional "highly correlated" items remained in the motor score. CMS should explain this inconsistency in their motor score design methodology.

Greater Transparency is Needed. The impact of the FY 2020 reforms is material for many IRFs, as noted above and our members having indicated that under the new CMGs and proposed motor score methodology, some patients' impairment level would drop substantially. Payment amounts for some patients with greater functional impairment also would drop. **These impactful and potentially harmful dynamics warrant a discussion by CMS of its policy objectives, as well as the agency's take on the resulting impact on patient access to care.** To increase transparency moving forward and enable stakeholders to replicate CMS's proposed policy changes, including their impact and possible alternatives, we ask the agency to begin sharing the following in each future proposed rule:

- Patient assessment data, which includes the current Section GG items used in developing the proposal;
- Matching claims data to derive ancillary charges; and
- Facility information to link to cost reports for case cost imputation or imputed cost data as used by CMS and its contractor (RTI).

In addition to their absence in the proposed rule, these data are not even available by order from CMS through the typical data acquisition process from ResDAC.

Concerns with Data Reliability. The simultaneous collection of two sets of different patient assessment data has created substantial administrative burden and confusion for providers, and required training staff on the new Section GG definitions and scales, as well as concurrent collection of the two sets of metrics. The rollout of the new quality indicators (QIs) was further inhibited by CMS's release of implementation guidance in a piecemeal fashion, including periodic revisions to the IRF-PAI

instruction manual and provider training, which has resulted in varying interpretations of CMS guidelines and inconsistent, rather than standardized, data collection. In addition, we note that since the new QIs are not used in the payment-setting process, they likely received less attention and resources during staff training and data collection – especially prior to CMS's issuance of the FY 2019 proposed rule, which announced the agency's plans to use the new data for payment setting beginning October 2019. The dual collection of both FIM™ and Section GG data, coupled with data collection guidelines that were evolving in real time, led to problems with the accuracy and validity of the resulting Section GG data. This resulted in at least a partially questionable data foundation for the proposed FY 2020 model. As such, we remain concerned that the data foundation of such a multi-faceted and impactful transition is partially based on relatively unreliable data.

Specifically, the FIM™ and Section GG data sets, while similar, use different scales, with the FIM™ instrument using a 0 to 7 point scale for motor and cognitive items. The QI motor function items use a 0 to 6 point scale and the cognitive function items using a 4 point scale. The compressed scale may limit the ability of the 22 QIs to fully capture the complexity of the sickest IRF patients, such as brain injury and spinal cord injury patients. In addition, the two sets of metrics use different definitions to assess patient performance, with the FIM™ items using a patient's lowest functional score and the new QIs using "usual performance." Since CMS has not shared its analysis of each Section GG QI's predictive power, it is difficult for providers to assess the distinct impact of each indicator on the new case-mix system. Further, the structure many of the QIs utilize is quite different from the comparable FIM™ items, such as the following proposed changes:

- An "admission roll left to right" indicator would be used in place of the FIM™ item on chair/bed-to-chair-transfers.
- Three "admission walk" indicators (for 10 feet, 50 feet with two turns, and 150 feet) with no wheelchair use, would be used in place of the FIM™ item on walking/wheelchair for 150 feet.
- An "admission one-step curb" indicator would be used in place of the FIM™ item on 12 stairs.
- "Admission bladder continence" and "admission bowel continence" indicators based on a seven-day assessment period would be used in place of a three-day period-based indicator.

**Moving forward, we urge CMS to address our concerns regarding the reliability of the FY 2017 QI data through further evaluation and validation of the FY 2020 case-mix system reforms by incorporating the most recent data in the model, as they become available. Doing so will help avoid unintended and harmful consequences with regard to reducing access to care for patients with conditions that are paid less under the new model due to possible unintended design limitations.**

## PROPOSED CLARIFICATION OF "REHABILITATION PHYSICIAN" DEFINITION

The AHA supports CMS's proposed clarification related to the existing regulatory definition of a rehabilitation physician: *"A licensed physician with specialized training and experience in inpatient rehabilitation."* **Specifically, we support the proposal to codify that each IRF can make its own determination regarding whether a physician qualifies as a rehabilitation physician under this existing definition.** Our members have expressed support for the additional flexibility. Specifically, while our IRF members often employ and are led by board-certified physiatrists, they report concerns that the supply of physiatrists is inadequate to support the exclusive reliance on board-certified physiatrists in the rehabilitation physician role. Moving forward, we encourage CMS to ensure high-quality care for IRF patients, especially those with high-acuity levels.

## QUALITY REPORTING-RELATED PROPOSALS

### IRF QUALITY REPORTING PROGRAM (QRP)

The Affordable Care Act mandated that reporting of quality measures for IRFs begin no later than FY 2014. Failure to comply with IRF QRP requirements will result in a 2.0 percentage point reduction to the IRF's annual market-basket update. For FY 2020, CMS would require IRFs to report 15 quality measures.

In the proposed rule, CMS proposes to add two measures to the FY 2022 IRF QRP. In addition, CMS would require IRFs to collect certain standardized patient assessment data beginning with IRF admissions on or after Oct. 1, 2020 to meet additional requirements under 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 adopt only measures that have received endorsement by the National Quality Forum (NQF). Furthermore, we urge CMS to reconsider its proposal to adopt the dozens of standardized patient assessment data elements all at one time and determine whether it is necessary or useful for IRFs 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 IRF 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 long-term care hospital (LTCH) QRPs. 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 as a concept several years ago. **However, we urge that the measure receive NQF endorsement before it is adopted in the IRF QRP.** We acknowledge NQF endorsement is not required for IRF 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 in which 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 only would mean 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. Although we understand how timely information sharing is associated with improved outcomes, it is hard to imagine how providers – or CMS – could determine whether this measure actually has any effect.

Transfer of Health Information to the Patient – PAC. CMS proposes to add this process measure to the FY 2022 IRF 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 LTCH QRPs. 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 IRF QRP.** In addition, we 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 – that is, patients who are admitted to the IRF following a long-term nursing facility stay with no intervening community discharge between the nursing facility stay and hospitalization prior to IRF 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 IRF 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 concerns raised by the AHA and other commenters 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 tested only 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 IRFs 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 24

SPADEs to the IRF-PAI, 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 24 new SPADEs – associated with potentially more than 60 new data elements to complete, depending on the patient – to the IRF-PAI all at one time would add administrative burden that far outweighs the benefit to patients or IRFs. Furthermore, the proposals fail 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 24 new data elements to the already lengthy IRF-PAI. Because many of these elements have multiple parts (i.e., a principal element and two to12 sub-elements 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 IRF-PAI (IRF-PAI 3.0) – including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection – is on average 86 minutes per response;[1] the proposed additional SPADEs would increase this time by approximately 22%. With approximately 319,000 IRF stays in 2016, the additional patient assessment tasks would result in **nearly 105,000 more hours of time spent on patient assessments per year.**

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 IRFs to collect and report several data elements whose relevance and value to care are dubious at best. Neither the passage of time since the FY 2018 rules nor CMS's efforts to reduce some burdens in the IRF QRP in the FY 2019 rulemaking process have created a sufficient ability to shoulder the burden that would suddenly be placed upon IRFs on Oct. 1, 2020. Even more troubling, CMS in this proposed rule requests feedback on the development of *even more* SPADEs. Unless the agency is planning to significantly reduce the current

[1] Department of Health and Human Services Center for Medicare & Medicaid Services Inpatient Rehabilitation Facility – Patient Assessment Instrument Paperwork Reduction Act Disclosure Statement, accessible: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/IRF-Quality-Reporting/Downloads/Final-IRF-PAI-Version-30-Effective-October-1-2019-FY2020.pdf

reporting burdens on PAC providers, it is unrealistic to mandate that providers comply with an exponentially growing list of reporting requirements. CMS's data collection proposal also runs counter to its Patients over Paperwork initiative that seeks to reduce the regulatory burden on providers.

Relevance and Reliability of Data Elements to IRFs. **The AHA is concerned that many of the proposed SPADEs appear to occur in IRF or PAC patients infrequently, thereby limiting the utility of the data collected.** The results of the national beta test show that many of the SPADEs in the Special Services, Treatments, and Interventions domain applied to less than 3% of IRF or PAC patients; in certain cases, 0% of IRF (and sometimes all 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: 1.7% of IRF patients demonstrated severely impaired vision.

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 already is 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 sub-element.
- Nutritional Approach: Mechanically Altered Diet: Reliability only moderate for IRF.
- 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.

The IMPACT Act mandated 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 IMAPCT 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.

Next, CMS notes that, if finalized, IRFs only would need to submit 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 would add to the confusion that already may 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 in the issue to ensure patient assessments are collecting the right data in the right way before these SDOH SPADEs are finalized.**

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