American Hospital Association

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June 26, 2018

Ms. 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-1688-P, Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2019

Dear Ms. Verma:

On behalf of our nearly 5,000 member hospitals, health systems and other health care organizations, including 1,272 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) 2019 proposed rule for the IRF prospective payment system (PPS). **Our comments address substantial concerns related to the proposed patient assessment and case-mix system changes**, as well as provide feedback on proposed changes related to the role of rehabilitation physicians in the IRF, hospital co-locations within an inpatient PPS-exempt hospital, and the IRF quality reporting program (QRP).

PROPOSED REVISION OF THE IRF PPS CASE-MIX SYSTEM

For FY 2020, CMS proposes to reform the current patient assessment process and case-mix systems of the IRF PPS. We are concerned that these new policies rely on inaccurate data, underestimate patient severity and are otherwise not transparent – all of which could adversely impact patient access, quality, and safety. The AHA recommends that, instead of finalizing its proposals, CMS should continue its development of a new system in collaboration with the field. We also suggest that this collaboration include a CMS technical expert panel to support the ongoing development of the proposal.

The proposed rule would remove FIM™ items and FIM™ function modifiers from the patient assessment and payment setting processes. In place of the FIM™ items, CMS would rely on quality indicators (QI) that already are included in the IRF-patient assessment instrument (PAI) implemented under the mandate of the Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014. As its rationale for these changes, CMS cites its burden-reduction goals. It also cites its broader effort to standardize data collection across post-acute care settings, as selected IRF-PAI items are similar to data elements used by skilled nursing facilities (SNFs) and long-term care hospitals (LTCHs). CMS also proposes modifications to the IRF payment units, called case-mix groups (CMGs), stating that such a revisions is warranted due to changes that have occurred since they were last revised, including changes in treatment patterns, technology, case-mix, and other factors that affect the relative use of resources across the classification system.

Insufficient Data Foundation. The QIs CMS proposes to rely on from IRF-PAI Section GG were implemented on Oct. 1, 2016. The collection of these new data coupled with the ongoing collection of FIM™ data created substantial administrative burden. The rollout of the QIs also caused significant confusion in the field since they are structured differently than the well-known FIM™ items, which use different definitions and scales. For example, there are several critical differences between the FIM™ items and the 22 QIs:

- The FIM™ instrument uses a 0 to 7 point scale for motor and cognitive items. In contrast, the QI motor function items use a 0 to 6 point scale and the cognitive function items generally use 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.
- The two sets of metrics also 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 the rule does not share CMS's analysis of each indicator's predictive power, it is difficult for providers to assess the distinct impact of each Section GG QI on the new case-mix system.
- In addition, 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; and
    - "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.

In addition to the challenges associated with switching to the different design, definitions and scales of the new indicators and the concurrent utilization of the two sets of metrics, the rollout of the new 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, as recently as spring 2018. Collectively, all of these factors led to struggles in training staff on the new QIs as well as challenges employing both sets of measures at the same time. **It is therefore reasonable to conclude that there are problems with the accuracy and validity of the resulting QI data – an issue that warrants additional attention from CMS, with results shared with the field.**

In addition, we note that since the new QIs are not used in the payment-setting process, they have likely received less attention and resources during staff training and data collection than they would have otherwise received. For this reason, like other data that do not influence payment, the QI data may be less accurate than FIM™ data. If that is the case, the QI data would be an inappropriate basis for the complex policy changes proposed in this rule. Given the proposed elevation of the role of these QIs to influence payment, we anticipate that these Section GG items will now be subject to far greater attention and resources for coding of these items, the fact remains that we have reason to question the accuracy of the past data. Also, we note that as a result of this new attention, the analytical impact of these data is likely to change. It would be appropriate for CMS to closely monitor any shifts in the outcomes for these data that are prompted by this rule, and update its model to capture any such shifts.

Further, given that the new QIs have thus far only yielded one year of data (from FY 2017), policymakers face a data set that is too small to support the proposed changes, which would materially change the structure and functionality of the IRF PPS. Rather, such a multi-faceted change should be based on multiple years of data that are considered to be relatively stable and valid. CMS should consider using subsequent data, which would help provide a more stable foundation to support this proposed policy change.

These concerns regarding the brevity and accuracy of the FY 2017 QI data cannot be overlooked. CMS must address them through further evaluation and validation through the use of most recent data. If CMS does not use a reliable data foundation, it runs the substantial risk of not only failing to achieve its worthwhile goals, but also of producing unintended and harmful consequences related to care planning and payment accuracy that are based on the IRF-PAI data – both of which must be optimized to ensure appropriate, high-quality and safe care.

<u>More Details are Needed Regarding Crosswalk to Proposed New CMGs</u>. Given the lack of analyses in the rule, AHA members and stakeholder partners are concerned about the proposed new CMGs' effect on calculating the severity of an IRF case. We are concerned that some of the Section GG quality indicators now being proposed for use in payment setting appear to inappropriately raise overall functional status, which would reduce the allocation of IRF resources. Specifically, analysis by Uniform Data System for Medical Rehabilitation's

(UDSMR) FY 2017 IRF discharges found that many of the new indicators show a higher rate of patients with maximum function (and, therefore, lower IRF needs). **The table below from UDSMR analysis shows that the Section GG QIs have notably higher rates of cases with average motor scores that maximized the scale, than those of the corresponding FIM™ item.** While these rates are substantially higher for each of the noted Section GG items, we particularly note that rate for the Section GG bladder item is almost double that of the corresponding FIM™ item and almost as disparate for the bowel items, as well.

Excerpt of 2018 Analysis by UDSMR	
IRF Average Scores per Indicator as a Percent of Maximum Function Comparing Motor Score Assessments Using FIM™ Indicators versus Corresponding GG Indicators	
SELECTED FIM™ ITEMS	**SELECTED SECTION GG ITEMS**
Admission Eating (39A)	**Admission Eating (Section GG0130A)**
67.3%	80.0%
Admission FIM Grooming (39B)	**Admission Oral Hygiene (GG0130B)**
54.6%	70.3%
Admission Bathing (39C)	**Admission Shower/bathe self (GG0130E)**
38.7%	45.1%
Admission Dressing - Upper (39D)	**Admission Upper-body dressing (GG0130F)**
44.7%	57.2%
Admission Dressing - Lower (39E)	**Admission Lower-body dressing (GG0130G)**
27.8%	39.2%
Admission Toileting (39F)	**Admission Toileting Hygiene (GG0130C)**
31.1%	44.0%
Admission Transfers - Bed/Chair/Wheelchair (39I)	**Admission Chair/bed-to-chair transfer (GG0170E)**
33.3%	46.8%
Admission Transfers - Toilet (39J)	**Admission Toilet transfer (GG0170F)**
36.0%	44.8%
Admission Locomotion - Stairs (39M)	**Admission One-step curb (GG0170M)**
20.5%	29.4%
Admission Sphincter Control - Bladder (39G)	**Admission Bladder Continence (H0350)**
42.5%	81.5%
Admission Sphincter Control - Bowel (39H)	**Admission Bowel Continence (H0400)**
55.7%	87.6%

Our concern is that in the most extreme cases, the crosswalk from the FIM™ items could yield a function status rating that results in IRF-appropriate patients actually being deemed ineligible for IRF services. In other words, the proposed rule is not sufficiently comprehensive to demonstrate that the cross-walk to the new system would reliably yield a clinically accurate severity assessment. In contrast, the FIM™ items have been subject to extensive evaluation by CMS and its contractors and have been expertly validated over their decades of use; as such, they are deemed reliable. To support a proposal that replaces the FIM™ items, CMS bears the responsibility of assuring stakeholders that its proposal does not adversely impact patients by understating their clinical status and needs.

It would be unwise to proceed with the proposed CMG changes if they could inadvertently understate patients' needs or underpay for services, which would result in patient safety and access challenges. Therefore, we urge CMS to expand its analyses of this aspect of its proposal and share those results with stakeholders to demonstrate that patients would not be adversely impacted by the design of new CMGs. In particular, it would be helpful if the agency shared both the clinical rationale and relative change in R^2 for each of the proposed new items that would be used to assign patients to a CMG. For example, sharing this information for the proposed new stairs and rolling-over indicators and the phase-out of the wheelchair metric, would help stakeholders understand the rationale for these changes, which appear to lower the standards used for CMG assignment, thereby assigning a higher functional level (which reduces the need for IRF services), relative to the corresponding FIM™ items. Using the wheelchair item as an example, CMS's rationale for making this change was mentioned in only a few sentences in the rule's companion technical report, which leaves the field uninformed about the need for and impact of this proposed change.

Greater Transparency is Needed. Moving forward, we urge CMS to increase the transparency of its analyses and proposals; the information contained in the proposed rule is insufficient. For example, CMS proposes to decrease the number of CMGs for stroke from 10 to six, which reduces the specificity of patient categorization and cuts payment for the most complex patients. However, CMS did not share with stakeholders the algorithms and regression trees used to design the proposed refinements that led to these and other changes. These same analyses were used to construct the new CMG framework and definitions, including the corresponding relative weights and average length of stay values. **The lack of transparency on these critical analyses has rendered providers unable to fully evaluate or replicate CMS's policy development process or outcomes.**

PROPOSED CHANGE TO CO-LOCATED SATELLITES

The AHA thanks CMS for its proposed changes to the separateness and control criteria that apply to satellite hospitals excluded from the inpatient PPS and co-located with another excluded hospital. Specifically, we support CMS's proposal to exempt satellites from Medicare separateness and control requirements, in line with changes made in FY 2018 for hospitals-within-a-hospital (HwHs). HwHs and satellites would still be held to these

requirements when co-located with an inpatient PPS hospital. We support CMS's rationale for these proposed changes, agreeing that the definitions for HwHs and satellites are significantly similar and their co-location policies have been based on many of the same concerns, most notably that patients would be inappropriately transferred from the host hospital to the co-located provider to maximize Medicare payment, rather than to optimize patient care. We appreciate CMS noting that such concerns have been "sufficiently moderated" and no compelling reason exists to treat satellites differently than HwHs with regard to the rules on separateness and control. We also note CMS's clarification that those co-located satellites that were excluded from the inpatient PPS before Oct. 1, 1995 remain exempt from the separateness and control requirements.

PROPOSED IRF COVERAGE REQUIREMENT CHANGES

The AHA appreciates CMS's proposals and solicitations related to the role of rehabilitation physicians, which are aligned with the agency's broader effort to reduce administrative burden for providers. We share the commitment to streamlining administrative burden when it can be achieved without reducing patients' access, safety, or quality of care.

Rehabilitation physicians lead the interdisciplinary care uniquely found in IRFs. Sometimes called physiatrists, **they treat a wide variety of medical conditions affecting the brain, spinal cord, nerves, bones, joints, ligaments, muscles, and tendons.** These specialized physicians have training and/or experience in the specialty of physical medicine and rehabilitation, and may be subspecialty certified in brain injury, hospice and palliative, neuromuscular, pain, and/or spinal cord injury medicine.

CMS has implemented stringent IRF admissions criteria to ensure that the setting remains uniquely focused on patients requiring hospital-level medical coordination in combination with intensive therapy. By overseeing these IRF services, rehabilitation physicians pay a critical part in executing this role. In fact, for an IRF claim to be considered medically necessary, there must be a reasonable expectation at the time of admission that the patient requires supervision by a rehabilitation physician. Today, the requirement for medical supervision in an IRF dictates that rehabilitation physicians conduct face-to-face patient visits at least three days per week to assess the patient both medically and functionally, as well as modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process. In addition, the patient's medical record must document whether the post-admission physician evaluation meets specified regulatory requirements. Further, IRF patients must require an interdisciplinary team approach to care, and such teams must meet on a weekly basis and be led by a rehabilitation physician.

Proposed Change to the Post-admission Physician Evaluation. **The AHA supports CMS's proposal to allow the post-admission physician evaluation to count as one of the three face-to-face physician visits required per week, as the physician, with three or more contacts per week, can achieve the full range of oversight required for both of these duties.** We agree that this change will provide greater flexibility and reduce redundancy and regulatory burden

while still ensuring adequate care to the patient. Further, we also believe that the clinical judgment of the rehabilitation physician should determine whether the patient needs to be seen more than three times in the first week of the IRF admission.

Proposed Change to Interdisciplinary Team Meetings. CMS also proposes to reduce burden by allowing a rehabilitation physician to participate in weekly meetings of the interdisciplinary team via video and telephone conference. CMS states that this change would increase time management flexibility for rehabilitation physicians, especially those in rural areas who may need to travel greater distances between facilities. **The AHA supports this change only as it pertains to rehabilitation physicians providing services in *rural IRFs*, as our rural members report that they often face unique challenges achieving reliable access to rehabilitation physician services.**

Solicitation of Comments Regarding Additional Changes to the Physician Supervision Requirement. **We oppose the move toward allowing rehabilitation physicians to remotely assess patients' medical and functional needs, as there are critical elements of the assessment that could not be comprehensively or safely implemented in a remote manner.** For example, several key physician functions require personal contact with the patient, such as evaluating a patient's functional potential to create an individualized, multidisciplinary plan of care and examining the patient throughout an IRF stay to manage and refine the plan of care. Any departure from these critical in-person functions would represent a meaningful dilution of the quality and intensity of care provided in IRFs.

Solicitation of Comments Regarding Changes to Use of Non-physician Practitioners (NPPs). **To help address existing rural physician recruitment and retention challenges, the AHA would be open to considering use of NPPs to supplement care delivery *in rural IRFs*.** Our support would depend on the details of the proposal and whether it generally delineates NPP versus rehabilitation physician roles in a manner that protects against any diminution of hospital-level, high-quality care for IRF patients.

CALL FOR FEEDBACK ON WAGE INDEX

In response to CMS's call for comments on potential changes to the Medicare wage index, we note IRFs are subject to wage index protocols that differ from those applied to other post-acute care providers. As a result, those providers in the same labor market are subject to inconsistent wage index adjustments. Specifically, the IRF PPS uses the prior year pre-classified acute care inpatient PPS wage index values, although this one-year lag is not applied to LTCHs or SNFs. Given that all of the post-acute care settings are on a track that may result in payment under a single, combined system, and the lack of a justification for this unique treatment of IRFs, **we ask CMS to explore harmonizing the different wage methodologies across all of these settings in a manner that eliminates the lagging update of wage-index reclassifications.**

PROPOSED CHANGES TO THE IRF QRP

The Affordable Care Act mandated the reporting of quality measures and that failure to comply with IRF QRP requirements will result in a 2.0 percentage point reduction to the IRF's annual market-basket update. Currently, CMS requires the reporting of 17 quality measures by IRFs. CMS proposes to remove two measures, one for the FY 2020 IRF QRP and one for the FY 2021 IRF QRP. **The AHA appreciates CMS's commitment to its Meaningful Measures initiative, which can be seen in the thoughtful analysis and removal of two measures from the IRF QRP. We encourage CMS to continue to apply the measure removal criteria to other measures in the IRF QRP, including those more recently adopted in the program, in order to reduce regulatory burden on providers so that they may focus instead on improving patient outcomes.**

FY 2020-2021 MEASUREMENT PROPOSALS

Proposed New Measure Removal Factor for Previously Adopted IRF QRP Measures. In previous rulemaking, CMS finalized seven factors to determine whether a measure should be removed from a QRP on a case-by-case basis. CMS proposes to expand the measure removal criteria by adding an eighth factor: "the costs associated with a measure outweigh the benefit of its continued use in the program." CMS defines "costs" as those affecting providers and clinicians, as well as the costs to the agency associated with program oversight. The agency also reiterates that the measure removal evaluation process would continue to be done on a case-by-case basis, and measures that are considered burdensome or "costly" might be retained in the QRP if the benefit to beneficiaries justifies the reporting burden. **The AHA supports the long overdue addition of this measure removal factor.**

Proposed Removal of the National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure. CMS proposes to remove this healthcare-associated infection outcome measure from the FY 2020 IRF QRP because a measure that is more strongly associated with desired patient outcomes for MRSA Bacteremia is available, namely the NHSN Central Line-associated Blood Stream Infection (CLABSI) Outcome Measure. The latter measure captures a wide range of bloodstream infections, including MRSA bacteremia; thus, the specific MRSA bacteremia measure is duplicative. In addition to this duplicative reporting burden, it is also costly for CMS to maintain both measures and potentially confusing for the public to have overlapping measure rates reported. **The AHA appreciates that CMS identified this duplication, and we support the measure's removal from the IRF QRP.**

Proposed Removal of the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) Measure. CMS proposes to remove this process measure from the FY 2021 IRF QRP as the agency has determined that the costs associated with the measure outweigh the benefit of its continued use in the program. In addition to near-perfect performance by providers on this measure in the 2016-2017

influenza season, CMS notes that data collection associated with the measure is more burdensome than beneficial. Patients are rarely admitted directly from an IRF; instead, patients are generally discharged from a general acute-care inpatient hospital to an IRF. It is during that proximal stay at the inpatient hospital that patients are nearly always given the flu shot; thus, most assessments at IRFs do not lead to vaccinations and end up as mere paperwork. **While the AHA agrees that influenza is a major issue for the vulnerable patients served by IRFs, we agree that the removal of the measure would not result in lower quality care and support its removal from the IRF QRP.**

Proposed Expanded Notification Methods for Noncompliance and Reconsiderations. CMS proposes to expand the methods by which the agency would provide notifications for decisions on noncompliance with IRF QRP requirements as well as reconsideration requests to include the Quality Improvement and Evaluation System Assessment Submission and Processing, the U.S. Postal Service, and email from the Medicare Administrative Contractors. **The AHA appreciates CMS responding to provider requests for more methods of communication and supports this change.** We also request additional details on the logistics of these methods of communication, including how providers will need to provide contact information to receive these notifications, who in provider organizations will be able to access the notifications, and a timeline for the change's implementation.

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, 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