June 17, 2019

Seema Verma, MPH
Administrator, Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS–1710–P
Mail Stop C4–26–05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System
        for Federal Fiscal Year 2020 and Updates to the IRF Quality Reporting Program

Dear Administrator Verma:

On behalf of the American Speech-Language-Hearing Association, I write to offer comments on the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal Fiscal Year 2020 and Updates to the IRF Quality Reporting Program for Federal Fiscal Year 2020 proposed rule and the development of the Standardized Patient Assessment Data Elements (SPADEs).

The American Speech-Language-Hearing Association (ASHA) is the national professional, scientific, and credentialing association for 204,000 members and affiliates who are audiologists; speech-language pathologists; speech, language, and hearing scientists; audiology and speech-language pathology support personnel; and students.

Standardized Patient Assessment Data Elements (SPADEs)
In the proposed rule, CMS suggests the use of several SPADEs beginning in 2022. These data elements were also proposed as part of the inpatient rehabilitation facility prospective payment system (IRF PPS) proposed rule and we anticipate their inclusion in the home health PPS proposed rule, which is likely to be released this summer.

ASHA appreciates that, at this time, the intent of these SPADEs is to assist with risk adjustment. We agree that, for this purpose, these SPADEs represent an appropriate start and we understand that it is CMS' intention to build upon these SPADEs for risk adjustment and quality. However, we must note that as currently structured the SPADEs cannot stand alone if CMS intends to truly improve the quality of care for Medicare beneficiaries and establish an accurate risk adjustment methodology.

The SPADE categories of primary interest to ASHA members include:
- Cognitive Function and Mental Status Data
- Special Services, Treatments, and Interventions Data
  - Cancer Treatment: Chemotherapy (IV, Oral, Other)
  - Cancer Treatment (Radiation)
  - Respiratory Treatment: Suctioning (Scheduled, as Needed)
  - Respiratory Treatment: Tracheostomy Care
  - Respiratory Treatment: Invasive Mechanical Ventilator
  - Nutritional Approach: Parenteral/IV Feeding
  - Nutritional Approach: Feeding Tube

- Nutritional Approach: Mechanically Altered Diet
- Medical Conditions and Comorbidities
  - Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities)
  - Impairment Data
    - Hearing

Cognitive Function and Mental Status Data
CMS proposes to include the Brief Interview of Mental Status (BIMS), the Confusion Assessment Method (CAM), and the Patient Health Questionnaire (PHQ) 2-9 as items to assess cognitive function. These screening assessment items may begin the process of assessing a patient's cognitive status but they do not address all areas associated with cognitive function and ASHA is committed to ensuring that CMS include a more comprehensive assessment of cognitive function in the assessment tools for post-acute care (PAC) settings as required by the Improving Medicare Post-Acute Transformation (IMPACT) Act.

ASHA is concerned that screening items, including BIMS, do not reliably detect the presence of mild cognitive impairment, differentiate mild cognitive impairment from a language impairment, or tie the impairment to functional limitation(s). The items in the BIMS provide insight into the patient's basic orientation to time and environment, but the limited assessment of memory as "OK" or "not OK" does not capture subtle problems in memory, problem solving, and executive function, which often interfere with a patient's safety, care planning, and eventual discharge status. Many patients who pass this basic screening remain at increased risk for injury or an unnecessary extended stay due to failure to detect a cognitive impairment and ensure prompt referral to a speech-language pathologist for further assessment and potential treatment. For this reason, ASHA continues to advocate for the use of the Development of Outpatient Therapy Payment Alternatives (DOTPA) items for post-acute assessments. DOTPA items, coupled with a functional screen to detect practical problems, need to be administered during PAC assessments.

The CAM is a standardized, evidence-based tool that enables non-psychiatrically trained clinicians to identify and recognize delirium quickly and accurately in both clinical and research settings. It is designed to specifically identify delirium only. It is likely too narrow in scope as a clinical tool for use in a skilled nursing facility environment. In addition, training to administer and score the tool is necessary to obtain valid results, and it is unclear how to ensure the person scoring the minimum data set (MDS) will be adequately trained to administer the CAM in the standardized format. The CAM was designed and validated to be scored based on observations made during brief but formal cognitive testing, such as brief mental status evaluations.[1] In the context of the MDS, it appears to be used outside its intended method as a standalone screener.

ASHA is concerned that the PHQ 2-9 assesses depression and it is not clear how that relates directly to cognitive function and the subsequent need for additional evaluation and potential treatment.

Special Services, Treatments, and Interventions Data
Overall, ASHA is concerned that the assessment items associated with the special services, treatments, and interventions section assess the presence or absence of something rather than the clinical rationale or patient outcomes. For example, while it is important to know that a patient is on a ventilator or a mechanically altered diet, it is also important to determine why this

intervention is necessary and what are the practical implications for the patient's quality of life and ability to participate in activities of daily living. We recognize assessing for the presence or absence of an intervention is an important first step in building an accurate and comprehensive assessment of the patient, but we must stress the importance of taking this to the next level and determining the impact and consequence of these interventions on patients.

A. **Cancer Treatment: Chemotherapy (IV, Oral, Other)**
The SPADE for Cancer Treatment Chemotherapy asks whether a patient is receiving chemotherapy and, if so, the method of administration. While it is important to know if a patient is receiving chemotherapy for cancer and the method of administration, the lack of an association with an outcome(s) is troubling. Implications of chemotherapy for patients needing speech-language pathology services include chemotherapy-related cognitive impairment, dysphagia, and speech and voice related deficits.

B. **Cancer Treatment (Radiation)**
The SPADE for radiation treatment asks if a patient is receiving radiation for cancer treatment. This does not help identify the rationale for and outcomes associated with this form of treatment. Implications of radiation for patients needing speech-language pathology services include reduced head and neck range of motion due to radiation or severe fibrosis, scar bands, and reconstructive surgery complications. These can impact both communication and swallowing abilities.

C. **Respiratory Treatment: Suctioning (Scheduled, as Needed)**
If CMS finalizes this provision of the proposed rule, the assessment tools for PAC settings would include an item to identify if a patient is receiving suctioning treatment and, if so, it the treatment is provided on a scheduled or as needed basis. The assessment tools should also assess the frequency of suctioning because this can impact resource utilization and potential medication changes in the plan of care.

D. **Respiratory Treatment: Tracheostomy Care**
CMS proposes to include an assessment item to determine if a patient is receiving tracheostomy care. This is an important data element for risk adjustment and can help identify increased resource utilization. However, CMS should consider building upon this item to ask the size of the tracheostomy and whether the tracheostomy has a cuff or is fenestrated.

E. **Respiratory Treatment: Invasive Mechanical Ventilator**
In a previous iteration of SPADEs association with invasive mechanical ventilation, CMS suggested the assessment item should indicate if the patient was weaned or not weaned from the ventilator. At that time, ASHA expressed concern that only assessing whether a patient was weaned or not weaned from a ventilator was inadequate because there are patients that are not appropriate candidates for ventilator weaning. It also failed to assess the quality of life for ventilator-dependent patients such as the ability to eat, drink, or communicate.

This iteration of a SPADE associated with invasive mechanical ventilator seems to be an unfortunate step back from the weaning/non-weaning version and only assesses whether the patient is on an invasive mechanical ventilator. Instead, CMS should consider collecting data to track functional outcomes related to progress towards independence in communication and swallowing. Often, tracheostomized and ventilator

dependent patients have long-term alternative feeding methods placed early in their acute medical course. Without speech-language pathology intervention, these patients may never return to an oral diet. Communication and swallowing management can greatly enhance the quality of life for individuals who are mechanically ventilated for the long-term.

F. **Nutritional Approach: Parenteral/IV Feeding**
CMS proposes several items associated with diet modifications including parental/IV feeding and mechanically altered diets. ASHA agrees that it is critical to capture information on these items to show the additional resources necessary to treat patients with altered diet needs, but they cannot be a substitute for items to capture information related to swallowing, which is also reflective of additional patient complexity and resource use. We are also concerned that, as proposed, these items show the method by which the patient receives nutrition, but not the clinical rationale for tube feeding or other forms of altered diet. For example, a patient who requires a mechanically altered diet due to absence of teeth, is very different in complexity and resource use from a stroke patient with moderate dysphagia who needs to be supervised by a trained staff person to ensure safe swallowing. As currently structured, swallowing data is not adequately captured.

G. **Nutritional Approach: Feeding Tube**
In addition to identifying if the patient is on a feeding tube or not, it is important to assess the patient's progression towards oral feeding as this impacts the tube feeding regimen.

H. **Nutritional Approach: Mechanically Altered Diet**
As currently structured, this SPADE does not capture clinical complexity and does not provide any insight into resource allocation (e.g., staffing needs for supervision). For example, a person on a mechanical soft diet after right hemisphere stroke presenting with left-sided neglect and impulsivity needs one-on-one supervision at mealtimes; whereas, a cognitively intact older adult with ill-fitting dentures who is on this same diet does not need similar supervision. Checking a single box that the patient needs a mechanically altered diet does not indicate what the patient needs for resources and care planning during the duration of their PAC stay.

Medical Conditions and Comorbidities
A. **Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities)**
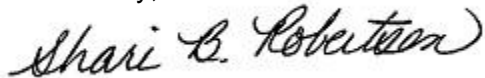CMS needs to consider the use of non-verbal means to allow patients to respond to the SPADE relating to pain. As it is currently structured and due to the complexity of answer choices, the question may not result in accurate information from those with cognitive and communication deficits. Existing non-verbal pain scales document pain intensity; whereas, this SPADE looks solely at pain frequency. It is important to identify both the frequency of pain and the intensity.

B. **Impairment Data (Hearing)**
ASHA is supportive of the current assessment item proposed for inclusion. However, CMS must first consider how hearing can be assessed to determine if hearing loss impacts a patient's ability to respond to the assessment tool in general (e.g., MDS, IRF-PAI) and subsequently participate in their care.

Thank you for the opportunity to provide comments on the IRF PPS FY2020 proposed rule. In summary, ASHA recommends that CMS actively build upon the SPADEs through future rulemaking. If you or your staff have any questions, please contact Sarah Warren, MA, ASHA's director for health care policy, Medicare at swarren@asha.org.

Sincerely,

Shari B. Robertson, PhD, CCC-SLP
2019 ASHA President

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[1] Inouye, S. K., van Dyck, C. H., Alessi, C. A., Balkin, S., Siegal, A. P., & Horwitz, R. I. (1990). Clarifying confusion: the confusion assessment method: a new method for detection of delirium. *Annals of internal medicine*, *113*(12), 941-948.