



September 5, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS-1711-P
P.O. Box 8013
Baltimore, MD 21244

RE: Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements

Dear Administrator Verma:

On behalf of the American Speech-Language-Hearing Association, I write to offer comments on the home health prospective payment system proposed rule for calendar year (CY) 2020 published in the *Federal Register* on July 18, 2019.

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.

Our comments address the following areas:

1. The need for therapy services regardless of the clinical grouping to which the patient is assigned;
2. The use of a Notice of Admission to enforce consolidated billing requirements;
3. The updates to the plan of care requirements;
4. The importance of monitoring OASIS, claims, and quality data to avoid stinting on care;
5. The use of therapy assistants to perform maintenance therapy; and
6. The identification of additional standardized patient assessment data elements (SPADEs).

The need for therapy services regardless of the clinical grouping to which the patient is assigned.

There are two reasons for moving from the current payment system to the Patient Driven Groupings Model (PDGM). First, PDGM removes the financial incentive to provide as many therapy visits as possible to maximize reimbursement and replaces it with payment associated with delivering care based on patient needs and the value of that care. ASHA supports this rationale. However, ASHA is concerned that the Centers for Medicare & Medicaid Services (CMS) makes a therapy payment to the home health agency (HHA) based on a patient's placement into a clinical group that qualifies for such a payment, regardless of whether or not the patient receives the medically necessary therapy they

need. Of the 12 clinical groups in the PDGM, only two recognize therapy services for payment despite CMS's stated expectation that therapy be delivered whenever medically necessary regardless of the patient's assigned clinical group.

From the inception of payment reform discussions initiated by CMS in 2017, ASHA has strongly advocated for mechanisms to ensure and confirm that patients receive therapy services when needed. ASHA recommends that CMS monitor and identify problematic trends that may indicate stinting on care. ASHA appreciates the following statement in the NPRM because of our commitment to ensuring access to medically necessary therapy services:

“While these clinical groups represent the primary reason for home health services during a 30-day period of care, this does not mean that they represent the only reason for home health services. While there are clinical groups where the primary reason for home health services is for therapy (for example, Musculoskeletal Rehabilitation) and other clinical groups where the primary reason for home health services is for nursing (for example, Complex Nursing Interventions), home health remains a multidisciplinary benefit and payment is bundled to cover all necessary home health services identified on the individualized home health plan of care. Therefore, regardless of the clinical group assignment, HHAs are required, in accordance with the home health CoPs at § 484.60(a)(2), to ensure that the individualized home health plan of care addresses all care needs, including the disciplines to provide such care.”

ASHA members report that they have heard their home health agency (HHA) employers discuss firing many or all therapists, including speech-language pathologists (SLPs), limiting the number of speech-language pathology visits, and restricting these visits to the first 30-day payment period of the 60-day episode. ASHA members also report that HHA's assert that PDGM does not allow clinicians to perform certain types of therapy services, such as cognitive therapy, within their scope of practice or to provide any therapy to patients outside of the two clinical groupings receiving a therapy specific payment. Any efforts, such as the statement above, that CMS makes to reinforce the critical role of therapy under the PDGM is valuable to maintaining access to medically necessary therapy services for Medicare beneficiaries.

The use of a Notice of Admission to enforce consolidated billing requirements.

The Balanced Budget Act (BBA) of 1997 (Pub. L. 105-33) requires consolidated billing. This means that the HHA must provide all medically necessary services for the patient and disallows billing for therapy services, including speech-language pathology services, provided by an SLP on an outpatient basis under Part B. ASHA is concerned that when the HHA fails to uphold its obligation to claim patients in a timely fashion and provide all medically necessary services, an SLP in private practice might treat these patients and attempt to bill Part B and be denied; even after exercising all due diligence. Subsequently, the clinician providing the outpatient care has no recourse for their services rendered.

In the proposed rule, CMS identifies a new mechanism to address the concerns raised by ASHA. CMS proposes to phase out the request for anticipated payment (RAP) by 2021 and

replace it with a required Notice of Admission (NOA). If an HHA did not complete an NOA within five days of the start of care, the HHA's payment would be reduced for services provided between the start of care and the submission of the NOA.

ASHA does not support the use of the RAP as a mechanism to incentivize HHAs to claim patients and ensure compliance with consolidated billing. As CMS stated in the 2019 OPPTS proposed rule, the RAP is at risk for fraud. In addition, given outpatient clinicians' experiences with denied claims, it does not seem to be an incentive the HHAs are using. ASHA supports the implementation of the NOA and encourages CMS to finalize the proposal as written including the elimination of the RAP.

The updates to the plan of care requirements.

In the proposed rule, CMS suggests streamlining the plan of care requirements at 42 Code of Federal Regulations (CFR) 409.43(a) to better align it with 42 CFR 464.40(a) and require the inclusion of the discipline(s) involved in the patient's care. ASHA supports requiring the identification of the discipline(s) involved in the patient's care in the individualized plan of care. The requirement will serve as an important mechanism to identify when HHAs do not deliver medically necessary therapy services and when the absence of therapy conflicts with the plan of care. Therefore, ASHA supports the modifications to the plan of care regulations as outlined in the proposed rule and requests that CMS finalize them.

The importance of monitoring OASIS, claims, and quality data to avoid stinting on care.

As noted above, ASHA is concerned that financial considerations will lead some HHAs to stint on therapy care to the detriment of Medicare beneficiaries. ASHA recommends that CMS identify mechanisms in claims, Outcomes and Assessment Information Set (OASIS), submissions and documentation requirements to mitigate these consequences. In addition, corresponding quality metrics will need to be identified and used to identify potential issues. Based on Tables 15 and 16 of the NPRM, ASHA notes that the payment differential between an HHA that submits the Quality Reporting Program (QRP) data and an HHA that does not submit this data is relatively minimal—approximately \$63 per episode. This amount does not provide a sufficient financial incentive to drive quality reporting and improvement. While the 2% reduction for failure to report this data is statutorily mandated, ASHA recommends that CMS identify additional ways to incentivize quality or advance the QRP to pay for performance.

Additionally, ASHA continues to stress the importance of identifying and implementing a cognitive function measure as required by the Improving Medicare Post-Acute Transformation (IMPACT) Act. While CMS has taken steps towards implementing such a measure, the currently adopted data elements, such as the Brief Interview of Mental Status (BIMS), do not address all the domains associated with cognitive function. ASHA again recommends the adoption of elements of the Care Tool, as was done with the mobility and self-care items, to capture quality in the area of cognition.

The use of therapy assistants to perform maintenance therapy.

As a result of the *Jimmo* settlement, CMS confirmed coverage of maintenance therapy in all settings with the exception of inpatient rehabilitation facilities (IRFs) where improvement is an explicit expectation. However, CMS has prohibited physical therapy assistants and occupational therapy assistants (PTAs and OTAs) from performing maintenance therapy under the home health and Part B benefits while allowing assistants to perform maintenance therapy in skilled nursing facilities (SNFs). Although Medicare does not recognize speech-language pathology assistants (SLPAs), ASHA supports establishing maintenance therapy policies to ensure recognition of assistants as qualified providers of therapy for both improvement and maintenance so that if in the future Medicare recognizes SLPAs, they may be appropriately integrated into all Medicare regulations.

CMS recognizes the ability of PTAs and OTAs to provide medically necessary therapy services under the supervision of a physical therapist or occupational therapist through the therapist-developed individualized plan of care. If a therapy assistant possesses the qualifications to perform services for the purposes of improvement, there is no clinical reason why they cannot perform maintenance therapy services. ASHA requests clarification regarding why CMS has established a distinction between maintenance therapy standards for SNFs and similar services provided in other settings by assistants. A uniform policy that recognizes assistants for the clinically indicated provision of improvement and maintenance therapy across practice settings is practical and would allow assistants to meet the needs of patients in rural and medically underserved areas where shortages of therapists exist.

ASHA recommends CMS to establish a maintenance therapy policy that allows assistants to provide these services while requiring regular engagement of the supervising therapist in direct patient care throughout the patient's episode of care to ensure the appropriate execution of the maintenance program.

The identification of additional 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 skilled nursing facility prospective payment system (SNF PPS) proposed rule.

ASHA appreciates that 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's intention to build upon these SPADEs for risk adjustment and quality. However, we must note that, as 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. As mentioned above, ASHA urges CMS to 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.

Screening items, including the 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 more 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 an SLP for further assessment and potential treatment. For these reasons, 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 identify delirium only. Its clinical scope is too narrow for effective use in a SNF environment. 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 Minimum Data Set (MDS), it appears to be used outside its intended method as a standalone screener.

The PHQ 2-9 assesses depression but it is not clear how that relates directly to cognitive function and the subsequent need for additional evaluation and potential treatment in the area of cognition.

Special Services, Treatments, and Interventions Data

ASHA notes 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. We recognize that assessing for the presence or absence of an intervention or condition constitutes an important first step in building an accurate and comprehensive assessment of the patient, but we stress the importance of taking this to the next level and determining the impact and consequence of these interventions and conditions on patients.

A. Cancer Treatment: Chemotherapy (IV, Oral, Other)

The SPADE for Cancer Treatment Chemotherapy asks whether a patient receives 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) fails to provide essential information. 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 receives 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, if 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 receives tracheostomy care, which represents 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 associated 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 provided inadequate information because some patients aren't appropriate candidates for

ventilator weaning. The SPADE 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, even from the weaning/non-weaning version, and only assesses whether the patient is on an invasive mechanical ventilator. Instead, ASHA recommends that CMS should collect data to track functional outcomes related to progress towards independence in communication and swallowing for ventilator patients. 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 rely on mechanical ventilation 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 supports capturing information on these items to show the additional resources necessary to treat patients with altered diet needs, but that limited approach cannot be a substitute for items to capture information related to swallowing, which also reflects additional patient complexity and resource use. ASHA is 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, presents differently in complexity and resource use from a patient who experienced a stroke and displays moderate dysphagia requiring supervision by a trained staff person to ensure safe swallowing. Currently, proposed measures do not adequately capture swallowing data.

G. Nutritional Approach: Feeding Tube

In addition to identifying the patient's feeding tube status, the patient's progression towards oral feeding requires attention because it impacts the tube feeding regimen developed by the SLP.

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 a 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, on this same diet does not need similar supervision. Checking a single box that the patient needs a mechanically altered diet does not accurately 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)

ASHA recommends that CMS implement nonverbal means to allow patients to respond to the SPADE relating to pain. As currently structured, and due to the complexity of answer choices, the question and allowed responses, may not result in accurate information from those with cognitive and communication deficits. Existing nonverbal pain scales document pain intensity; whereas, this SPADE looks solely at pain frequency. ASHA recommends the identification of both the frequency of pain and intensity of pain.

B. Impairment Data (Hearing)

ASHA supports 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.

In conclusion, ASHA recommends that CMS:

1. Reinforce the requirement that HHAs provide all medically necessary services, including speech-language pathology services, regardless of clinical grouping at every available opportunity; including through rulemaking and provider education resources;
2. Finalize its proposal to eliminate the RAP and implement an NOA;
3. Update the plan of care requirements at 42 CFR 409.43(a) as proposed;
4. Identify mechanisms to utilize QRP requirements to avoid stinting on care;
5. Allow therapy assistants to perform maintenance therapy; and
6. Refine SPADEs over time to ensure Medicare quality reporting programs live up to their promise to improve the quality and value of services Medicare beneficiaries receive.

Thank you for the opportunity to comment on this proposed rule. If you or your staff have questions, please contact Sarah Warren, MA, ASHA's director for health care policy for Medicare, at swarren@asha.org.

Sincerely,



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

¹ Inouye, S. K., van Dyck, C. H., Alessi, C. A., Balkin, S., Siegel, 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.