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Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1748-P
P.O. Box 8016
Baltimore, MD 21244-8016

Submitted via regulations.gov

Re: CMS-1747-P: Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-term Care Hospital Quality Reporting Program Requirements

On behalf of Uniform Data System for Medical Rehabilitation (UDSMR) and the nearly nine hundred inpatient rehabilitation facilities we provide services to, we are pleased to present our comments on CMS-1747-P: Medicare and Medicaid Programs; CY 2022 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model Requirements and Proposed Model Expansion; Home Health Quality Reporting Requirements; Home Infusion Therapy Services Requirements; Survey and Enforcement Requirements for Hospice Programs; Medicare Provider Enrollment Requirements; Inpatient Rehabilitation Facility Quality Reporting Program Requirements; and Long-term Care Hospital Quality Reporting Program Requirements. With over thirty years of experience, UDSMR provides coding, clinical, quality improvement, and technical support services to IRFs and other postacute care (PAC) providers. UDSMR appreciates the opportunity to provide ongoing feedback to CMS and hopes to work with CMS toward solutions that meet the needs of IRF providers and patients.

UDSMR is providing comments specifically on Section IX.A, "Proposal of a Revised Compliance Date for Certain Inpatient Rehabilitation Facility (IRF) QRP Reporting Requirements." Although we and our subscribers appreciate CMS's desire to address the concepts of health equity and interoperability by using standardized patient assessment data elements (SPADEs) related to social determinants of health (SDOH) and transfer of health (TOH) information, the continued impact of the COVID-19 public health emergency (PHE) will negatively affect IRFs' ability to implement version 4.0 of the IRF-PAI 0 on October 1, 2022, as proposed. We recommend that CMS not implement this proposal at this time and that it instead abide by the conditions in IFC-2 (85 FR 27550), which states that implementation of the TOH measures and collection of data in IRF-PAI version 4.0 will not begin until October 1 of the year that is at least one full fiscal year after the end of the COVID-19 PHE.

COVID-19 and the delta variant continue to surge in areas across the United States, causing IRFs to scatter resources, convert beds from inpatient rehab to acute care, and even temporarily close in some cases. Vaccine mandates in some states, counties, and cities, as well as mandates from some private health-care entities, are negatively affecting the availability of clinicians and other health-care staff, which diminishes the ability of IRFs to provide the intensive level of care their patients require. In combination, the surge and vaccine mandates severely limit the availability of resources needed to plan, prepare, educate, and train on TOH measures and SPADEs in order to implement IRF-PAI version 4.0 by October 1, 2022.

IRF-PAI version 4.0 is a thirty-page assessment form that nearly doubles the amount of information contained in the existing eighteen-page IRF-PAI version 3.0. In the FY 2020 IRF final rule (CMS–1710–F), CMS estimated that the collection of TOH data would add 1.2 minutes of clinical staff time per patient stay and that the additional SPADEs would add 7.8 minutes on admission and 10.95 minutes on discharge for a total of 18.8 minutes per patient stay. CMS further suggested that "the newly adopted IRF QRP quality measures and standardized patient assessment data elements will result in a burden addition of $7,339 per IRF annually, and $8,234,450 for all IRFs annually." As UDSMR and our subscribers indicated in comments to CMS-1710-P, these estimates are significantly understated. They do not include the amount of time needed to train and educate staff on the new SPADEs and do not include the amount of time needed to facilitate the collection of information from the patient, especially for SPADEs that require posing a question to a patient and receiving the patient's response. For patients with significant cognitive deficits, the collection of the new SPADEs may require additional time in order to not only ensure that the patient understands the questions posed but also allow sufficient time for the patient to communicate a response that is both reliable and valid. This additional time, when added to the time required to meet standards of care during the COVID PHE, will negatively affect the health-care workforce and the reliability and validity of the information being collected.

UDSMR also notes that CMS has not provided sufficient information to suggest that the collection of this information will meet the standards of the IMPACT Act, the Meaningful Measures Framework, and the Patients over Paperwork initiative. According to materials shared by CMS during its Special Open Door Forums and National Beta Test results meetings, the evaluation of SPADEs for implementation should be based on four main characteristics and their underlying criteria:

1. Potential for improving quality
    a. Improve care transitions, person-centered care, and care planning
    b. Improve care practices and patient safety
    c. Use for quality comparisons, including value-based payment models
    d. Supports clinical decision-making and care coordination
2. Validity and reliability
    a. Interrater reliability (consensus in ratings by two or more assessors)
    b. Validity (captures the construct being assessed)
3. Feasibility for PAC use
    a. Potential to be standardized and made interoperable across settings

   b. Clinically appropriate
   c. Relevance to workflow
4. Utility for describing case mix
   a. Potential use for payment models
   b. Measures differences in severity levels related to resource needs

CMS has provided some information suggesting that SPADEs meet the "validity and reliability" and "feasibility for use in PAC" characteristics noted above, and National Beta Test documents have provided interrater reliability testing results indicating that the information is reliable and valid. CMS has also cited current use in other PAC settings, as well as the qualitative results of National Beta Test surveys, as demonstrating that the proposed SPADEs are "clinically useful" or may be feasible for data collection. Despite all this, however, CMS has not provided any evidence that the proposed SPADEs have the "potential for improving quality" or "utility for describing case mix," which are two key characteristics for evaluating SPADEs for implementation.

With respect to the "potential for improving quality," CMS has not supplied quantitative evidence that the results of the National Beta Test offer the ability to meet any of the criteria noted above. Even simple frequencies of responses would allow IRFs and other PAC providers to determine whether these SPADEs should be collected for quality comparisons or for supporting clinical decision-making. The failure to supply even this basic level of information suggests the possibility that underlying issues will prevent this data from meeting this consideration.

In terms of the "utility for describing case mix," CMS has again not provided any quantitative information suggesting that the SPADEs are capable of meeting these criteria for consideration. We note that CMS and RTI International have not identified the response frequency for each SPADE as part of the National Beta Test. Without seeing how these SPADEs tested on IRF patients, IRFs cannot evaluate whether the SPADEs have the potential for use in payment models or have the ability to measure differences in patient severity.

CMS should release additional quantitative information from the National Beta Test that provides evidence that the SPADEs measure what they are intended to measure and that they can be used for quality and/or payment.

We also have the following additional concerns related to the proposed implementation of SPADEs:

- IRFs are currently collecting data elements for the Brief Interview for Mental Status (BIMS) even though these elements have not demonstrated the ability to predict costs or differentiate case mix. CMS has not provided any additional evidence to suggest that the BIMS is capable of being utilized for quality purposes to support the collection of these data elements at discharge.
- Although IRFs are seeking additional information related to cognitive status, it is unclear as to whether the addition of the CAM and PHQ-2 to 9 data elements will identify differences in cognitive status or measure changes during the stay resulting from therapeutic interventions. Additionally, there are concerns about the reliability and validity of the PHQ-2 to 9 data elements and their patient-reported outcomes for patients

with severe cognitive deficits, prior mental health issues, or noncommunicative conditions.

- The collection of certain elements at both admission and discharge adds unnecessary administrative burden for patient characteristics that are not anticipated to change from admission to discharge. For example, the preferred language, need for an interpreter, and lack of transportation data elements should be assessed only once during a patient's stay.
- Although potentially useful in determining resource needs, the collection of the Special Treatments, Procedures, and Programs data elements at both admission and discharge creates additional administrative burden when these circumstances may already be present on claims data or are capable of being determined through data elements already captured on the IRF-PAI (e.g., comorbidity ICD-10 codes).
- CMS's timing estimates are significantly understated. IRFs that participated in the National Beta Test indicated that time studies were based only on the time needed to enter a value on a tablet and did not include the time required to evaluate the patient for each item.

UDSMR has the following recommendations with respect to the implementation of the SPADEs:

1. CMS should evaluate whether SPADEs are already captured by other means, such as IRF-PAI assessment data or billing/claims data. Language in the IMPACT Act suggests that duplicative data elements are to be removed. The proposed SPADEs may be unnecessary if they are duplicative.
2. CMS should reduce data collection for elements that will not differ between admission and discharge.
3. Until the prior recommendations are met, CMS should not finalize the SPADES' implementation. This decision will help IRFs avoid unnecessary administrative burden and will adhere to principles of the Meaningful Measures and Patients over Paperwork initiatives.

For the reasons noted above, UDSMR recommends that CMS not implement IRF-PAI version 4.0 on October 1, 2022. At a minimum, we recommend that CMS abide by the conditions in IFC-2 (85 FR 27550), which states that implementation of the TOH measures and collection of SPADEs data in IRF-PAI version 4.0 will not begin until October 1 of the year that is at least one full fiscal year after the end of the COVID-19 PHE. We believe that a continued delay of the implementation will provide IRFs with adequate opportunities to respond to additional surges in patients, accommodate any need to replenish the health-care workforce, and ensure that sufficient time is available to educate and train staff about new data elements in order to provide reliable and valid data for payment and quality purposes. We also recommend that during this continued delay, CMS should provide additional information on each of the new SPADEs in IRF-PAI version 4.0 from the National Beta Test or any other sources that address concerns about the administrative burden and whether these items will differentiate case mix for payment or differentiate provider performance for quality.

We appreciate both the opportunity to comment on this proposed rule and CMS's careful consideration of the concerns and issues raised in this letter. With over thirty years of experience providing coding, clinical, and quality improvement services to IRFs and other PAC providers, UDSMR welcomes the opportunity to work with CMS to provide ongoing feedback regarding the selection and implementation of standardized and interoperable quality indicators and standardized patient assessment data. If you have any questions about these comments or require additional information, please contact us at 716-817-7800.

Sincerely,

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