September 8, 2019

Ms. Seema Verma  
Administrator, Centers for Medicare and Medicaid Services  
Hubert H. Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

Re: 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 Ms. Verma,

On behalf of the Coalition to Transform Advanced Care (C-TAC), we appreciate the opportunity to provide comments on this proposed rule in regard to its effects on those living with advanced illness.

C-TAC is a national non-partisan, not-for-profit organization dedicated to ensuring that all those living with advanced illness, especially the sickest and most vulnerable, receive comprehensive, high-quality, person- and family-centered care that is consistent with their goals and values and honors their dignity. C-TAC is made up of over 140 national and regional organizations including patient and consumer advocacy groups, practitioners, health plans, faith-based and community organizations, and others who share a common vision of improving advanced illness care in the U.S.

C-TAC’s definition of advanced illness is when one or more conditions becomes serious enough that general health and functioning begin to decline, treatment may no longer lead to preferred outcomes, and care oriented toward comfort may take precedence over attempts to cure – a process that extends to the end of life and that for some individuals and their families may lead to transition to hospice.

The proposed Home Health rule has several aspects that will affect those with advanced illness. Here are our specific comments:

**Implementation of the Patient-Driven Grouping Model (PDGM)**

We appreciate that the goal of this model is to better align payment with patient care needs and ensure that clinically complex and ill beneficiaries have adequate access to home health care. However, our home health members have shared their concerns that this will be very complicated to administer and could inadvertently impede access for just such
patients as a result. It would be unfortunate, for instance, if home health agencies (HHA's) were to reluctant to take on complicated patients, many of whom would likely have advanced illnesses, because of the complexities of this model.

While we do not have suggestions for ways to simplify it, we would encourage you to work with HHA’s, and the home health industry, to find a better way to implement this important model.

**Proposed Changes to the Home Health Plan of Care Regulations**

We very much appreciated the inclusion of “information related to any advanced directives” in the current regulations. Such directives are the foundation of good care and should be required to be assessed in all Medicare programs. While we also acknowledge that the current language and interpretation caused administrative and financial problems for HHA’s, we would encourage you to include some reference to advance directives in the final rule along with reference to medical orders such as POLST. The best way for an “individualized plan of care” that specifies “the services necessary to meet the patient-specific needs identified in the comprehensive assessment” is for that plan of care to reference the person’s goals, values, and treatment preferences. That information is ideally found in an advance directive and, to a lesser extent, a POLST. Of course, Medicare beneficiaries have every right to decline to participate in advance care planning, but that refusal could be noted and the HHA not penalized for it. Therefore, we do not support the proposed revision and would instead have some inclusion of the presence of advanced directives and/or POLST orders in some fashion.

We would also note the correct term is “advance” directives, not “advanced” as they are done in advance of the need for medical care.

**CMS Proposal to Remove Improvement in Pain Interfering with Activity Measure (NQF #0177)**

We agreed with the statement on page 206 of the proposed rule: “Pain is not a surprising symptom in PAC patients and residents, where healing, recovery, and rehabilitation often require regaining mobility and other functions after an acute event. Standardized assessment of pain that interferes with function is an important first step toward appropriate pain management in PAC settings”.

We are therefore surprised and in *strong disagreement* with the removal of the Pain Interference measure from the HH QRP. As further noted in the proposed rule, this decision is not based on any evidence, which undermines the goal of evidence-based policy. Pain is a key reason for hospital admission and to not measure it in home health makes no sense and could result in poor pain management necessitating further ED or hospital visits. Pain interference with activities is a good way to measure the impact of this unpleasant symptom and should be mandatory in all Medicare programs.

In addition, HHA’s are not the organizations typically prescribing opioids for home health patients, so it is unclear how not requiring them to report on this measure would change
prescribing practice. Instead, we are concerned that it would add to the fears clinicians and the public have about opioid medications. These fears can undermine appropriate opioid use for those with chronic pain, such as a third of cancer survivors\(^{i}\), and many with advanced illness. Therefore, we urge you to retain this important measure.

**HH QRP Quality Measure Proposals Beginning with the FY 2022 SNF QRP**

- **Proposed Transfer of Health Information to the Provider–Post-Acute Care (PAC) Measure:** We support the addition of this measure as many of those with advanced illness have complicated medication regimens and assessing whether or not a current reconciled medication list is given to the HHA, when a patient is discharged or transferred from his or her current PAC setting, is critical. These transitions are often when mistakes and deletions occur and that jeopardizes the care and safety of such vulnerable patients.

- **Proposed Transfer of Health Information to the Patient–Post-Acute Care (PAC) Measure:** We support the addition of this provision from the IMPACT Act as it is also helpful and assessing whether or not a current reconciled medication list was provided to the patient, family, or caregiver when the patient was discharged from a PAC setting to an assisted living, group home, transitional living or personal home under care of an organized home health service organization will help ensure that patients and their families have the latest and correct medication information in that setting.

**HH QRP Quality Measures, Measure Concepts, and Standardized Patient Assessment Data Elements under Consideration for Future Years: Request for Information**

- **Standardized Data Elements**
  - We support the move to standardized data elements and the ones provided in this proposed rule on Table 27. Our only concerns regard the following data elements:
    - **Functional maintenance outcomes:** While we agree with the inclusion of data elements to assess function, we want to note that maintaining function is eventually not possible for those with many advanced illnesses which are typically progressive and, ultimately, result in debility and death. Therefore, this data element should not penalize HHA’s caring for patients who will not be able to maintain function.
    - **Opioid use and frequency:** While monitoring opioid use is important, we do not want such a data element to in any way discourage the appropriate use of opioids for pain or dyspnea management in beneficiaries receiving care from a HHA. We note that some HHA’s are expanding their services to include home-based palliative care and that such a measure could discourage them from caring for palliative care patients, some of whom appropriately require higher doses of opioids.
    - **Caregiver status:** Beyond the measure concepts listed, we would encourage CMS to define what is meant by “caregiver status” as we believe an assessment of the family caregiver’s understanding of their loved one’s
medical situation, home care, and the caregiver’s stress level are all aspects that should be included under such a “status” concept.

- **Health disparities and risk factors**: We would suggest additional elements such as housing and food insecurity as these are important risk factors that HHA’s would be well situated to help identify and address.

- **High-Risk Drug Classes: Use and Indication**: This data element contains two classes of drugs used by palliative care providers for those with advanced or serious illness: opioids and antipsychotics. While we agreed with the proposal that the HHA assess each patient for use of any of these classes and then confirm that the use is warranted, we want to make sure that this assessment does not inadvertently discourage appropriate use of these medications in these populations. Additionally, we would not want such a drug class to discourage HHA from caring for patients appropriately taking these medications.

**One additional measure concept for consideration**

- **Timely and appropriate referral to hospice**: As HHA providers provide care to patients with advanced illness more frequently, either through the provision of community-based palliative care or through the HH benefit, there is often a time when the transition to hospice should be considered. This measure concept would ensure that a hospice referral is considered and that the patient’s eligibility for hospice is considered and offered. A process measure, for example, could capture that goals of care or advance planning occurred; a claims based outcome measure, for example, could capture the % of home health beneficiaries that transition to die in hospice and of those hospice patients, measures of timely referral base on hospice LOS i.e. <7days, median.

**Collecting standardized patient assessment data**

- **Medical Condition and Comorbidity Data Elements**
  As noted earlier, we strongly support the measurement of “Pain Interference (Pain Effect on Sleep, Pain Interference with Therapy Activities, and Pain Interference with Day-to-Day Activities)” and with adding it since this measure addresses an important aspect of care for those with advanced illness. The concerns for opioid overuse notwithstanding, those who receive care at home should have “pain interference” measured and treated with whatever treatment is effective, including opioids when appropriate.

- **Proposed Social Determinants of Health (SDOH) Data Collection to Inform Measures and Other Purposes**
  We support the use of the seven proposed SDOH elements, “race, ethnicity, preferred language, interpreter services, health literacy, transportation, and social
isolation.” We also suggest the CMS explore family caregiver assessment as a possible future social risk as the health and capability of the family caregiver for someone with advanced illness can have a significant impact on their health and medical interventions. Many with advanced illness need assistance, which is where the presence of social risk factors of their family caregivers can be an issue\textsuperscript{iii}. Also, as noted earlier, we suggest adding housing and food security as additional future elements as they also impact health and health care utilization.

Thank you for the opportunity to comment on this draft strategy. If you have any questions, please contact Marian Grant, Senior Regulatory Advisor, C-TAC, at 443-742-8872 or mgrant@thectac.org.

Sincerely,

*Marian Grant*

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