September 16, 2019

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

Re: Specialty Care Models to Improve Quality of Care and Reduce Expenditures

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.

Overall, we support both the Radiation Oncology (RO) and Endstage Renal Disease (ESRD) models as we feel they will significantly improve care for those living with cancer and ESRD. Here are our specific comments:

**RADIATION ONCOLOGY MODEL**

**Quality Measures and Reporting Requirements**

- Preventive Care and Screening: Screening for Depression and Follow-Up Plan - NQF #0418; CMS Quality ID #134- We support the inclusion of this measure as depression is found in up to 24% of those with cancer and is therefore important to be assessed and addressed.
• **Advance Care Plan -NQF #0326; CMS Quality ID #047**: We strongly support the inclusion of this measure. Advance care planning is a key activity for those with cancer, as identifying their goals and values should result in more personalized care plans.\(^{i}\) (For that reason, this measure should be included in all Medicare models and programs.) Of course, patients have every right to decline to participate in advance care planning, but that refusal could be noted, and the participating provider not penalized for it.

• **Timely and appropriate referral to hospice**: As some people receiving RT will be getting it for palliative purposes, that is also when the transition to hospice should be considered. We therefore suggest a measure concept to ensure that a hospice referral is considered in such cases and that the patient’s eligibility for hospice is assessed and hospice offered. A process measure, for example, could capture that goals of care or advance care planning occurred. Claims-based outcome measures could capture the percent of model beneficiaries that transition to hospice and, of those hospice patients, whether referral to hospice was timely based on hospice length of stay, i.e. less than seven days, etc.

**Beneficiary Freedom of Choice**
We support this concept as it is important that the model’s structure and requirements not interfere with the care that a person and their health care provider determine is best for them. Participating in this model should improve the quality and cost of care, not limit people’s treatment options.

**Availability of Services**
We support necessary services being available to those who want and need them and appreciate the safeguards being proposed in this model to ensure that.

**Proposed RO Model Participants**
We support the participant criteria with the exception of excluding those in a Medicare hospice benefit period. Such patients may benefit from radiation oncology treatment as a palliative measure and so should be allowed to participate in this model, if so. While we agree this is a reimbursement issue for hospices, palliative radiation is by its nature not curative and so should be covered under the Medicare hospice benefit, at least for those people with cancer participating in this model.

**Proposed Included Radiotherapy Services**
We strongly recommend including palliative care as a required additional service in this model. The evidence supports that people who receive symptom management and psychosocial support are more likely and better able to complete cancer treatment and to have better outcomes.\(^{ii}\) Other evidence suggests they may even live longer.\(^{iv}\)

In addition, the National Comprehensive Cancer Network (NCCN) guidelines\(^{v}\) include
access to palliative care for those with cancer from diagnosis on, as do the latest American Society of Oncology (ASCO) Clinical Practice Guidelines\textsuperscript{vi}. Therefore, palliative care should be required to be available under this model.

**Monitoring**

We support the proposed monitoring activities, particularly activities i, ii, and iv: “that the participant: (i) has discussed goals of care with each RO beneficiary before initiating treatment and communicated to the RO beneficiary whether the treatment intent is curative or palliative; (ii) adheres to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or document in the medical record the rationale for the departure from these guidelines; and (iv) assesses the RO beneficiary’s performance status as a quantitative measure determined by the physician”. As noted previously, goals of care are necessary to ascertain in order to ensure the best care, the NCCN and ASCP guidelines include access to palliative care, and performance status is a very important aspect to monitor.

**ESRD MODEL**

We are in support of this model and of CMS’ efforts to improve care for those with ESRD by, first, preventing kidney failure and, then, promoting other treatment options beyond clinic-based hemodialysis including peritoneal dialysis and kidney transplant. We are reminded of the importance of promoting other options by a recent Journal of the American Medical Association (JAMA) study showing lower rates of transplantation for patients receiving care at for-profit dialysis centers.\textsuperscript{vii}

**Beneficiary Exclusions**

- **Medicare hospice beneficiaries**- As noted above for the RO model, we suggest not excluding those in a Medicare hospice benefit period. Peritoneal dialysis is less costly than clinic-based hemodialysis and so may be something hospices could offer to continue for patients, especially those for whom ESRD is not their terminal diagnosis. Only 20% of the ESRD population receives hospice care\textsuperscript{viii} and most of those only for a short period of time as they usually have to forego hemodialysis. By including them in this model, they and their families could more fully benefit from this valuable type of end-of-life care.

- **Dementia**- We support the exclusion of those with a diagnosis of dementia. Additionally, we’d ask that CMS consider carefully all policies related to the provision of hemodialysis for individuals with moderate to advanced dementia that impairs their decision-making capacity. Going to a clinic and being hooked up to a dialysis machine is likely challenging and may be inappropriate for patients who lack the cognitive ability to choose and/or tolerate that treatment.

- **Advanced age**- In regard to possibly excluding those with advanced age, the proposed rule notes there is little evidence to support such an exclusion. We agree that beneficiaries should not be excluded only on the basis of age but suggest that it is not a person’s age that should be the determining factor but their functional
status. The evidence is growing that hemodialysis for frail elders does not meaningfully improve or prolong their lives and comes with a great burden. For that reason, we suggest that CMS consider carefully all policies related to the provision of hemodialysis for those with poor functional status to ensure that they support appropriate care and honor individual treatment choice.

**Quality Measures**

We recommend adding the following measures:

- **NQF measure on advance care planning**- This should be a required measure for this model as it is for the RO model. There is evidence that many individuals are receiving hemodialysis without a good understanding of their prognosis. Including advance care planning in this model would ensure that there is a conversation about the person’s medical status, prognosis, and their goals and values so as to ensure that the choice to participate in any form of ESRD treatment is truly informed.

- **Timely and appropriate referral to hospice**- As noted in our RO model comments, some of the patients in this model will likely be in the last months of life and therefore, the transition to hospice should be promoted. We suggest a measure concept to ensure that a hospice referral is considered in such cases and that the patient’s eligibility for hospice is assessed and hospice offered. A process measure, for example, could capture that goals of care or advance care planning occurred. Claims-based outcome measures could capture the percent of model beneficiaries that transition to hospice and of those hospice patients, whether referral to hospice was timely based on hospice length of stay, i.e. less than seven days, etc.

**Palliative care**

We strongly recommend adding palliative care as a required available service under this model. As noted, many who currently opt for hemodialysis do so with limited understanding of their prognosis and or discussion of their personal values and goals. These are critical to ensure that the treatment they select is in line with those values. Living with ESRD can be difficult for the person and their loved ones, and palliative care can help provide an extra layer of support while improving quality of life. Recent data shows that only 2.7% of those with ESRD received a palliative care consultation. Currently, CMS only requires palliative care be included in the process for a Ventricular Assist Device (VAD). We have long felt that this requirement needs to be broadened to other high burden/high cost treatments such as hemodialysis. This model is an ideal opportunity to do so.

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

Sincerely,

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6 https://ascopubs.org/doi/full/10.1200/EDBK_175474
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