September 16, 2019

VIA ELECTRONIC MAIL

Seema Verma
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD, 21244

Re: Specialty Care Models To Improve Quality of Care and Reduce Expenditures (CMS-5527-P)

Dear Administrator Verma:

The Health Care Transformation Task Force (HCTTF or Task Force) thanks the Centers for Medicare and Medicaid Services (CMS) for the opportunity to respond to the proposed rule on Radiation Oncology (RO) and End-Stage Renal Disease (ESRD) Treatment Choices (ETC) models (Proposed Rule).

The Task Force is a consortium of over 40 private sector stakeholders that support accelerating the pace of transforming the delivery system into one that better pays for value. Representing a diverse set of organizations from various segments of the industry – including providers, health plans, employers, and consumers – we share a common commitment to transform our respective businesses and clinical models to deliver better health and better care at reduced costs. Our member organizations aspire to have 75 percent of their business in value-based arrangements by 2020. We strive to provide a critical mass of policy, operational, and technical support that, when combined with the work being done by CMS and other public and private stakeholders, can increase the momentum of delivery system transformation.

We appreciate that CMS is committed to designing more Advanced Alternative Payment Models (Advanced APMs) that provide opportunities to specialists who currently have few options to participate in value-based payment models. HCTTF applauds CMS for acknowledging
this issue and working to create openings for specialists to become Qualifying APM Participants (QPs).

The Task Force believes that clinical episode-related payments can promote high-quality, high-value and transparent care for Medicare beneficiaries and can encourage greater coordination among providers. HCTTF regularly provides CMS with constructive feedback regarding APMs, including a recent communication providing suggested design considerations for mandatory models.\(^1\) Our comments offered herein reflect a desire to increase the transparency of mandatory model rulemaking for required participants, to bring the proposed quality measures into alignment with other models and the care delivery goals of the proposed models, and to ensure that proper exclusions are made to ensure patient safety and the delivery of appropriate clinical care.

I. General

The Task Force strongly encourages the inclusion of stakeholders in the design of mandatory models; as CMS continues to iterate on these models, we urge the agency to meaningfully engage stakeholders throughout the process. Transparency, simplicity, and advanced notice of required participation are critical to smooth and efficient model implementation and success. As model refinement continues, the Task Force asks CMS to consider the general feedback below in design of any model, but most importantly, those models that require participation.

A. Participant notice and selection

In our recommendations to CMMI on designing mandatory value-based payment models, HCTTF requested that CMS offer Advanced Notice of Proposed Rulemaking (ANPRM) public comment periods in addition to a formal Notice of Proposed Rulemaking (NPRM) or alternately, issue an Interim Final Rule with a public comment period. Given that these models did not have an ANPRM comment period or specify which geographic regions are mandatory, **Task Force members request that CMS issue an Interim Final Rule with Public Comment Period— with the selected participants identified in the Interim Final Rule— to ensure meaningful stakeholder engagement and constructive design recommendations in addition to adequate time for providers to prepare for the model.**

Prior CMS mandatory models specified the geographic regions for which participation would be mandatory in the proposed rule. This advanced notice allowed providers to adequately prepare for the model and consider its impact on their practices and partners in the region. HCTTF members are concerned that the Proposed Rule signals a CMS move away from

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\(^3\) [https://hcttf.org/recommendations-mandatory-models/](https://hcttf.org/recommendations-mandatory-models/)
this practice because it does not specify proposed regions. The absence of selected regions in the Proposed Rule creates a disincentive for providers and supplier participants to analyze model impact and submit constructive recommendations on the proposed model design.

**B. Performance period**

Task Force members have expressed concern with the Proposed Rule’s proposed start date of January 1, 2020, for a few reasons, including those noted above regarding advanced notice. This start date presents a constrained timeline for new participants to prepare and to invest in and implement necessary infrastructure. This concern is heightened given CMS’s expressed intent to mandate participation for providers and suppliers that are unlikely to participate in voluntary models and are therefore less likely to have experience managing downside-risk. These challenges are exacerbated by the fact that many providers are still deciding whether to participate in the recently released Direct Contracting models for which key details necessary for decision-making remain outstanding, including details about how that model would interact with other APMs.

As proposed, the models do not include a performance year zero (PY0) similar to other recently released models. The Task Force recommends CMS include a PY0 for the RO and ESRD ETC models to serve as a baseline measurement and preparation period, similar to the Direct Contracting model. Implementing a PY0 will allow providers additional time to make changes needed to support the new models and adequately recognize the time needed to implement care transformation initiatives. This would also alleviate the concern that future success in the model is necessitated by initial performance in the first year.

**C. Overlap with other models**

HCTTF has previously shared feedback with CMS regarding the importance of considering model overlap in the design of new APMs. In addition to providing APM participants with adequate flexibility to manage overlap based on their unique market situation, Task Force members believe strongly that the goal of these models should be to fundamentally change care delivery and improve population health, rather than seeking opportunities to leverage market dynamics to reduce costs. The Task Force is concerned that the proposed models don’t place sufficient emphasis on population health and encouraging providers to keep patients from getting to later disease stages in the first place.

**D. Initial risk-sharing levels**

The Task Force has asked that CMS design any mandatory models with the option for participants to accept gradual increases in risk-sharing. Both the RO and ETC proposed models increase risk-sharing over time; however, the Task Force members are concerned by the significant downside risk levels at the initial stages of the program. We urge CMS to lower the

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initial downside risk levels for both programs to encourage participants to commit resources and make early investments to be successful in the model. Hospitals and providers need to build the infrastructure necessary to comply with program specifics at the beginning of the program and effectively implement the care delivery changes envisioned by CMS.

E. Rigorous Evaluation to Ensure Beneficiary Protections & Track Unintended Consequences

HCTTF asks CMS to provide in an Interim or Final Rule specific information regarding how the Agency will monitor and intervene on potential unintended consequences that may result from the mandatory models. To prevent any unintended adverse effects on patients, CMS should ensure that strong patient protections and rigorous rapid-cycle evaluation are included in the models. If rapid-cycle evaluations reveal that a model is reducing quality of care or restricting access to care, CMS should move to immediately terminate the model. CMS should also publicly report the results of these evaluations to allow the health care sector to learn and benefit from the findings.

II. Radiation Oncology Model

A. Pricing methodology

CMS anticipates the RO model would encourage more efficient care delivery and incentivize higher value care across episodes of care. However, HCTTF is concerned that the proposed discount factor on participant-specific payment amounts (four percent for the professional component and five percent for the technical component) when combined with the upfront withholds will create substantial disruption to the financial stability of RO participants and negatively impact their ability to improve efficiency and provide high-quality care to Medicare beneficiaries. **We request that CMS reevaluate the downside-only design of the discount and withhold process and the penalty for historically-efficient providers to ensure that access to care is not adversely impacted under the model.** The additional two percent reconciliation withhold, two percent professional component withhold for quality, and one percent technical component withhold for beneficiary experience will cause significant decreases in cash flow, despite the opportunity to earn back a portion of that withhold later in the model.

B. Coordination between separate episode components

CMS has proposed to trigger an episode only if a Technical participant or Dual participant furnishes the technical component (TC) to an RO beneficiary within 28 days of when a Professional participant or Dual participant furnishes the professional component (PC) to such RO beneficiary. HCTTF members have expressed concern regarding the disconnect in timing between the professional component and technical component such that a PC-only participant may have very little insight into whether a TC-only participant provided the RT service within the
28 days window; conversely, providers participating as a TC-only participant may not have adequate insight into the start of an episode when billing for the technical component or knowledge of whether it was done in the timeline the model indicates. **CMS should offer a solution to support improved coordination between professional and technical component participants that are not Dual participants, including sharing claims data as close to real-time as possible.**

**C. Quality measures and withhold**

The Task Force supports CMS’s efforts to select performance metrics that measure performance improvement and patient experience. However, our members are concerned about the one percent component of the two percent quality withhold applicable to professional participants that requires reporting on clinical data elements for 95 percent of all patients with one of five cancer types (prostate, breast, lung, bone metastases, and brain metastases) that are not currently captured in structured fields by all major EHR vendors. CMS has structured this as a pass/fail measure to earn back the quality withhold but has not established any clinical or payment-related rationale to support the collection of this patient-identifiable data. The clinical data under the RO Model would not be used for risk adjustment, as it is used in administering OCM. This data is currently reported to state cancer registries, but the deadlines for cancer registry reporting for states are later than the deadlines proposed for RO. Therefore, **we do not believe CMS should mandate that participants report this data because it will impose a redundant reporting burden and expense for participants to extract this data without any reasonably justified need for CMS to have the data.**

**III. End-Stage Renal Disease Treatment Choices Model**

**A. Home Dialysis and Transplant Performance Assessment and Performance Payment Adjustment**

CMS has proposed to adjust certain payments for ETC participants during the Home Dialysis and Transplant Performance Assessment and Performance Payment Adjustment (PPA) period based on the ETC participant’s home dialysis rate and transplant rate during the corresponding Measurement Year. As currently drafted, the PPA would apply to claims through dates beginning January 1, 2021. Our members are concerned that the introduction of the payment adjustment this early in the model does not recognize the time and investments needed to meaningfully increase home dialysis rates. Concurrently, CMS will need to undertake a substantial beneficiary and provider education effort to support this model, which will both take time to develop and to implement. HCTTF therefore recommends that CMS delay the application of the PPA until later performance years.

The Task Force is also concerned that the PPA does not consider the needs of vulnerable patient populations nor account for clinical appropriateness of home dialysis. Home dialysis requires adequate square footage, access to a full-time caregiver, and is only feasible in a sterile environment. This could preclude patients with unmet social needs such as housing insecurity.
from safely receiving home dialysis. Additionally, home dialysis may not be clinically appropriate for all patients. Regarding the transplant rate, there are several factors outside of the control of proposed ETC participants. The facility and transplant rates do not incorporate consideration of the availability of organs, nor the individual patients’ clinical indication for transplant. To account for these variables, **CMS should include appropriate patient acuity and additional adjustments, including those that assess SDOH and unmet social needs, in calculating the home dialysis and transplant rates and issuing the PPA.**

Lastly, our members are concerned with the significant downside adjustment (negative six percent) to all MCP and 072X claims in Year 1 of the model. **We recommend that CMS lower this rate in the earlier years of the model to encourage meaningful care transformation rather than trivial cost-cutting.** The six percent downside adjustment in Year 1 is significant for a provider to take on as they are getting adjusted to the model. This does not provide adequate onramp time to build out a clinical model and infrastructure necessary to succeed under a new payment model.

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The Task Force appreciates the opportunity to provide comments on the mandatory models proposed rulemaking and stands ready to assist CMS as these models are finalized and implemented. As noted above, the Task Force is concerned about the lack of transparency regarding mandatory model participants and the ability to ensure the delivery of appropriate clinical care and patient safety under the proposed models. We reiterate our desire for additional opportunities to comment on an interim rule prior to CMS issuing a final rule. Please contact HCTTF Executive Director Jeff Micklos (jeff.micklos@hcttf.org or 202.774.1415) with questions related to this statement.

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