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June 2, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
The U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

RE: Radiation Oncology Model CM-5527-P2

Dear Administrator Brooks-LaSure:

The American College of Radiology (ACR), representing nearly 40,000 diagnostic radiologists, interventional radiologists, radiation oncologists, nuclear medicine physicians and medical physicists, appreciates the opportunity to provide comments on the Radiation Oncology Model (RO Model) proposed rule issued on April 6, 2022. We appreciate the opportunity to respond to the Agency's proposal to indefinitely delay the RO Model.

The ACR believes with modifications to the RO Model, the model would prove successful. The ACR believes the RO Model worthy goals remain within reach if there are changes made to the model. The ACR is committed to working with the Agency, Congress, and other stakeholders to make the necessary reforms to the RO Model. The ACR is also supportive of undertaking a new payment reform initiative that would contribute to President Biden's strategy for fighting cancer. We remain committed to these ideals and believe that a successful transition to value-based payment for radiation oncology is still achievable. However, before focusing on what comes next, whether that be a broader total cost of care (TCOC) or oncology accountable care type concept, we think it is important to review the RO Model, its flaws and our recommended fixes, so that this experience can be used to inform future initiatives. The ACR remains concerned on several aspects of the models.

Mandatory Participation

CMS identified practices in select Core Based Statistical Areas (CBSAs) for mandatory participation in the RO Model. The ACR remains concerned about the mandatory participation requirement of the RO Model. Requiring one group of practices to transition to a new payment model and bear the burden of generating all of the identified savings associated with the model is a significant concern, particularly given that the model has never been tested. The ACR has supported voluntary participation in a radiation oncology APM, and we remain apprehensive about a model that requires mandatory participation at the beginning. This expansive mandatory model goes far beyond any demonstration program that CMS has put into place and could jeopardize access to radiation care in vulnerable populations. The ACR is very concerned about the effects this model will have with the inclusion of small and rural practices entering risk-based arrangements without sufficient resources. If CMS decides to move forward with the RO Model, ***ACR urges CMS to initiate it on a voluntary basis with little to no risk.***

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Payment Methodology

The ACR continues to have concerns surrounding the complex payment methodology used in the model. The RO Model is a “site neutral test” that establishes a common National Base Rate for services regardless of where they are furnished. CMS utilizes historical Hospital Outpatient Department (HOPD) episode payment data as the foundation for the development of National Base Rates for the Professional Component (PC) and Technical Component (TC) payment for each of the 15 disease sites. The ACR remains concerned about CMS’ decision to establish the site neutral test based on OPSS data alone, a blend of the historical PFS and OPSS rates for the PC of each cancer type will establish more accurate payment rates.

Discount Factor Cuts

In the 2022 OPSS final rule, CMS finalized discount factors of 3.5% on the PC payment and 4.5% on the TC payment. The ACR previously recommended that CMS permanently reduce the discount factors in the model. The ACR urged CMS in a [letter](#) to the Agency in October 2020, the ACR recommends that CMS reduce the discount factors to no more than 3%. Reducing the discount factors further will help this model be more consistent with MACRA’s intent. ***We continue to believe that the Agency should set the discounts at 3% or less.*** Additionally, discount factors at this level will allow practices to continue investing in the equipment necessary to deliver high quality cancer care.

Quality Measures and Clinical Data Elements

The ACR strongly cautions against requiring manual reporting of CDEs through a CMS-provided template, and RO-Model electronic portal since these mechanisms are not included in MIPS. Given these concerns a two-year ramp up period should be instituted before requiring regular CDE reporting. A two-year period would allow clinicians the appropriate amount of time to develop workflows to consistently document the proposed data elements and provide time for vendors to accommodate the relevant radiation oncology data standards development that is occurring within the mCODE¹² and CodeX¹³ initiatives. Additionally, time is needed to modify and adopt software for the tasks related to clinical data elements and to clarify gaps and ambiguities in the instructions involving the clinical data element and engage in necessary training. CMS must consider a gradual requirement that starts at 25% of RO beneficiary episodes in the first performance period, growing to 75% over the duration of the RO Model demonstration period. This would align with the stepped approach that CMS took with the MIPS quality measures reporting requirements.

Monitoring Requirements

As mentioned in previous comment letters, the monitoring requirements are not the issue, they are process of care activities that are meaningful and indicate a certain level of high-quality treatment. However, the ACR is concerned that EHR vendors need time to develop discrete fields for the requested monitoring data elements, as they may be typically captured in clinical notes or external systems, but not in EHRs. While vendors can build something to be compliant, a new build can take between 12 and 18 months. Once the build is complete, practices must then implement and incorporate into workflows, taking even more time. Additionally, there is no reimbursement associated with the monitoring requirements—only the excessive payment cuts. ACR remains concerned regarding the related financial costs that participants will incur due to mandatory participation in the RO Model.

Given that the CMS has yet to provide additional clarifying guidance regarding how the Agency expects practices to collect and report on this data, the ACR recommends that compliance be voluntary until specific guidance is issued; EHR vendors have had the opportunity to develop the necessary software for the collection of the data; and RO Model participating practices have been able to upgrade their existing systems.

Practices should not be penalized due to CMS' lack of guidance related to the monitoring requirements. An alternative and more simplified approach to these monitoring requirements would be to establish an accreditation requirement as part of the RO Model.

Achieving Health Care Equity in Cancer Care

In the CY 2022 HOPPS final rule, CMS stated it has no evidence or data to suggest the RO Model will worsen health disparities. The Agency believes that the model presents opportunities to minimize health disparities that currently exist through the reduction of treatments under the episode-based payment approach, which may lead to reduced side effects from treatment, reduced travel time required for treatment, and less time spent in a doctor's office. Additionally, the Agency asserts that participants will benefit from collaboration on performance improvement and shared communication platforms that allow participants to learn from their peer network and share best practices. The Agency commits to providing quality feedback reports so that practices can understand individual patterns of care delivery and compare their data with similar RO Model participants so they can identify opportunities for quality improvement.

Impact on Rural Communities

A recent analysis demonstrates that there is a significant disparity between urban and rural RO Model participants capacity to deliver high value treatments, such as stereotactic and brachytherapy services.¹ Radiation oncologists that provide care in rural communities or to underserved populations experience several challenges related to participation in any type of payment model, whether it be episode based or total cost of care (TCOC). Clinics in rural or underserved communities serve patients who are more likely to be covered by Medicare or Medicaid programs, rather than privately funded employer-based health plans. Due to this payer mix, this group of physicians typically has more limited financial resources than their peers in other areas. This makes it difficult to invest in the resources necessary to participate in value-based payment programs.

A lack of capital funding puts these practices at a disadvantage when it comes to investing in newer, more efficient technology, as well as the upgrades in EHR systems for quality measures reporting, both of which are necessary for successful participation. The limitation on financial resources also limits their ability to hire staff to perform the administrative services associated with participation. Frequently, in clinics that provide care to rural communities or medically underserved areas, the radiation oncologist wears more than just the physician's hat, they are also billing and claims adjudication professionals and practice administrators.

Shift Towards Total Cost of Care Models

The ACR appreciates CMS's desire to shift toward a Total Cost of Care (TCOC) or Accountable Care Organization (ACO) type concept for oncology services, we urge CMS to consider the appropriateness of episode-based payment within broader TCOC and ACO models. One of the tenets of value-based care is the development of alternative payment models that allow physicians to manage the costs that they can control. This concept has remained out of reach for most radiologists. The ACR believes that radiation therapy is an appropriate candidate for episode-based payment since it is a distinct component of care within the broader cancer care continuum. Under a total cost of care model that includes medical oncology and radiation oncology services, there remains a significant risk that radiation oncology will be underutilized as drug prices

¹ Mantz CA, Thaker NG, Pendyala P, Hubbard A, Eichler TJ, Shah C, Orio PF 3rd, Petereit DG. Disproportionate Negative Impact of the Radiation Oncology Alternative Payment Model on Rural Providers: A Cost Identification Analysis of Medicare Claims. *JCO Oncol Pract.* 2021 Sep 16:OP2100330. doi: 10.1200/OP.21.00330. Epub ahead of print. PMID: 34529516.

continue to escalate. TCOC models must find ways to better align incentives that take into consideration the providers and costs involved in downstream services.

Importance of Quality

The ACR remains concerned that one of the reasons CMS has failed to implement the RO Model is due to an overemphasis on model savings. We would argue that the shift to value-based payment should focus heavily on quality and practice transformation, which will lead to lower costs. However, there is a critical opportunity to improve the quality of care and achieve practice transformation, with subsequent incremental savings, through the adoption of shorter course treatments that are guideline concordant.

The ACR appreciates the opportunity to comment on RO Model proposed rule. We hope you find these comments provide valuable input for your consideration. If you have any questions, please contact Christina Berry, Team Lead Economic Policy at cberry@acr.org.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "William T. Thorwarth, Jr. MD, FACR". The signature is fluid and cursive, with a large initial "W" and "T".

William T. Thorwarth, Jr., MD, FACR
Chief Executive Officer