The US Oncology Network

September 17, 2021

VIA ELECTRONIC SUBMISSION THROUGH www.regulations.gov

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
P.O. Box 8010
Baltimore, MD 21244-1850

Re: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Administrator Brooks-LaSure:

On behalf of The US Oncology Network ("The Network"), one of the nation's largest and most innovative networks of community-based oncology physicians, treating over a million cancer patients annually in more than 450 locations across 25 states, thank you for the opportunity to comment on the CY 2022 Hospital Outpatient Prospective Payment System (OPPS) proposed rule, which includes proposed modifications to the Radiation Oncology (RO) Model.

The Network has long been a strong proponent of value-based care because it motivates better quality, outcomes, and patient experience at a sustainable cost. We are committed to working with the Centers for Medicare and Medicaid Services (CMS) to provide patient access to high-quality, affordable care, in the most efficient setting. This commitment is demonstrated by the more than 900 Network physicians participating in the Oncology Care Model (OCM), who are successfully bending the cost curve in oncology and have achieved nearly $200 million in combined savings for the Medicare program.

The Network has also advocated for an alternative payment model for radiation oncology to promote quality outcomes and provide payment stability. Since CMS first issued the *Specialty Care Models To Improve Quality of Care and Reduce Expenditures* proposed rule in July 2019, to the final rule issued in October 2020 and subsequent correction to the final rule issued in December 2020, The Network has thoughtfully reviewed each iteration of the RO Model, and provided substantive and informed feedback to CMS in both formal comments and meetings. We have established a dedicated Network RO Alternative Payment Model (APM) Office to analyze the Model and advise on operational changes, quality metrics, and billing requirements to help practices prepare for implementation.

Unfortunately, despite the two full years that have passed since the RO Model was originally proposed, we are still waiting on a number of critical pieces of information and guidance from CMS to inform our practices' ability to successfully participate in the Model. In fact, we can't help but observe meaningful differences in CMS' willingness to be forthcoming with this mandatory model in comparison to the more collaborative approach CMS took with the implementation of the OCM, which is a voluntary model. Similarly, CMS has only made marginal changes to the financial impact of the RO Model, holding firm, for example, to a discount factor that remains above what has been proposed in other APMs.

Further, it is critical that CMS take into account the broader impact of other, simultaneous policies that will all affect freestanding radiation oncology practices. The CY 2022 Physician Fee Schedule (PFS) proposed rule calls for a -8.75% reduction to radiation oncology, plus an additional -2.0% reduction after the COVID-related sequestration moratorium expires. Practices in the RO Model will feel the effects of the payment cuts in the CY 2022 PFS through services that are still paid fee-for-service and through the Model's trend factor, particularly for those with sites in and out of the Model. When combined with the significant operational burden the Model imposes as well as the persistent financial and administrative challenges related to the COVID-19 pandemic, it is hard to see how this Model won't lead to further consolidation of freestanding radiation practices into larger health systems.

As further detailed in our comments below, The Network urges CMS to adopt the following recommendations in order to advance meaningful practice transformation and maintain the viability of freestanding radiation therapy centers:

- Reduce the discount factor to 3.0% for both the Professional Component and Technical Component;
- Modify the trend factor to prevent additional downside risk and provide payment stability;
- Provide the 5% APM incentive bonus for technical payments;
- Delay Clinical Data Element reporting for two-years.

To facilitate your review, we have broken our comments into the following sections:

<u>Savings Target</u>

CMS estimates that the policies in the CY 2022 OPPS proposed rule, including the changes in the baseline period, the removal of brachytherapy and liver cancer, and reduced discount factors, will result in $160 million in savings to Medicare over a 5-year model performance period; this is a decrease from the $230 million that was estimated in the Specialty Care Models final rule issued in September 2020. At the same time, CMS estimates that physician group practices will see a 5.5% increase over the five-year life of the Model, and a 1.8% increase in 2022.

Frankly, these projected impacts have been difficult to validate because CMS has yet to provide case mix and historical experience adjustment data inputs and it has yet to release the Medicare claims data files. This makes it especially difficult to comment on the proposed rule as well as prepare for model implementation at the practice level. The Network has 34 sites across 15 practices that have been mandated to participate in the RO Model. This significant footprint gives us the ability to examine the impact of the Model across multiple practices, yet our internal analysis indicates that similar practices will experience very different effects from the RO Model. This variation across sites cannot be explained simply through differences in practice patterns. While we appreciate the delayed start of the RO Model as practices weather the effects of COVID-19, CMS' delay in providing this data has prevented practices from taking full advantage of the additional time. **The Network urges CMS to provide this data so the practices who are mandated to participate in the RO Model can fully understand its financial implications and plan ahead.**

Additionally, CMS' estimated impact in the CY 2022 OPPS proposed rule does not include the payment cuts called for in the CY 2022 PFS proposed rule. The Network estimates that the financial impact of the CY 2022 PFS proposed rule on radiation oncology could exceed -13% in 2022 due to policy changes in the rule combined with the lapse of the temporary conversion factor increase and sequestration relief. The RO Model would impose an additional $160 million in cuts to participants over the next 5 years. **The Network urges CMS to consider the holistic impact of cuts stemming from the RO Model, the PFS, and the COVID-19 pandemic to freestanding oncology practices to ensure the Model doesn't lead to further consolidation.**

Discount Factor

CMS proposes to lower the discount factor for the Professional Component (PC) from 3.75% to 3.5% and the discount factor for the Technical Component (TC) from 4.75% to 4.5%. Again, when taken together, the discount factor, the undervalued base rates, the trend factor, the withholds, and adjustments will result in a payment reduction to practices well beyond the MACRA nominal risk requirement and the discounts seen in other Advanced APMs (AAPMs). With the significant payment cuts proposed in the CY 2022 PFS proposed rule, **The Network urges CMS to reduce the discount factor for both the PC and the TC to 3.0%.**

Trend Factor

Practices mandated to participate in the RO Model are forced to accept an upfront payment reduction with the promise of more stability than they would receive in fee-for-service. However, the RO Model's trend factor is designed to adjust the national base rates to reflect current trends in the OPPS and PFS rates for radiation therapy services. Therefore, if the PFS and OPPS experience significant reductions, this has a compounding effect on participating practices. As we have discussed with CMMI, payment stability is critical because radiation is a fixed cost business with significant upfront capital costs and ongoing, incremental costs as practices make necessary investments in new technology. Practices will not be able to make those investments in a model that has significant payment variability. The reimbursement rates in the CY 2022 PFS proposed rule are a key example of this, as radiation oncology faces a -8.75% reduction, before sequestration, with certain services down as much as -22%. **The Network urges CMS to modify the trend factor to prevent additional downside risk and provide payment stability**.

Cancer Types

CMS is proposing to remove liver cancer from the list of cancer types included in the RO Model because it now believes it does not meet the inclusion criteria because liver cancer is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines. The Network supports this proposal and agrees that liver cancer should be removed from the list of cancer types in the Model.

Included Services

CMS is proposing to remove brachytherapy as an included modality in the RO Model in response to stakeholder concerns about how multi-modality episodes are handled in the Model and whether it could create a disincentive to refer patients to other radiation oncologists for treatment when the RO participant cannot deliver brachytherapy services themselves. We share this concern and are pleased that CMS is addressing it. In our comments on the proposed rule issued in 2019, we noted that the National Base Rates for prostate cancer and gynecological malignancies appeared to be driven by large volumes of patients who received external beam radiation treatment (EBRT) alone, which did not reflect standard clinical practice of combined treatment with EBRT and brachytherapy. The Network recommended that brachytherapy services be reimbursed as fee-for-service for patients who are also receiving EBRT, or that CMS create additional diagnostic groups for multi-modality treatment. We applaud CMS for listening to these concerns. That said, we share the American Society for Radiation Oncology's (ASTRO) concerns that this modification does not fully address broader concerns regarding adequate reimbursement for brachytherapy services.

Advanced APM and MIPS-APM Status

Two Track Approach: In the 2022 OPPS proposed rule, CMS proposes to designate participating practices as "Track One" or "Track Two." CMS proposes to define "Track One" to mean an AAPM and MIPS APM track for Dual participants and Professional participants that use CEHRT. RO Model participants in Track One will be considered to be participating in the Advanced APM track of the RO Model, and CMS will make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track One. If eligible clinicians who are Track One participants do not meet the established QP thresholds, they will be considered MIPS-APM participants. CMS proposes to define

"Track Two" to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements set forth at § 512.220 and for all Technical participants. RO participants that fall into Track Two will not be considered as an AAPM or MIPS APM for the RO Model. CMS emphasizes that any failure to comply with the requirements of § 512.220(a)(2) will result in Track Two status for the RO participant and would be subject to remedial action under § 512.160.

The Network finds the RO Model requirements in § 512.220 to be clinically relevant and appropriate for inclusion in the RO Model. However, we are concerned that the proposal to designate practices as Track One or Track Two would unnecessarily narrow eligibility for AAPM and MIPS-APM status. Because practices are required to participate in the Model and will likely experience payment cuts while meeting the quality measures, further reducing their opportunity to qualify for the AAPM bonus, particularly in cases of minor noncompliance with the monitoring requirements in § 512.220(a)(2), is incongruent with the spirit of an APM, which is to incentivize high quality care. We also share ASTRO's concerns that electronic medical record (EMR) vendors will need time to develop the fields necessary to capture the monitoring data elements.

Waiver of 5% Bonus on Technical Component Services: In the RO Model final rule released in 2020, CMMI finalized its proposal to waive the 2015 Medicare Access and CHIP Reauthorization (MACRA) requirements to include TC payments in the calculation of the 5% APM Incentive Payment. **The Network continues to strongly disagree with this policy and urges CMS to apply the bonus to the technical payments for freestanding practices.** The overarching goal of an APM is practice transformation, which requires financial investment. For the RO Model, this includes software, EMR and IT updates, new workflows, as well as quality metric and other data documentation, collection, and reporting, along with the necessary outside services and personnel. Declining to provide incentive payments in the RO Model to assist physicians' and practices' transition toward value-based payment appears directly counter to MACRA's intent.

Clinical Data Element (CDE) Reporting: As included in comments submitted to CMS on the RO Model Quality Measure and CDE Collection and Submission Guide, **The Network strongly urges CMS to consider a two-year delay of the CDE reporting.** We share ASTRO's concerns around the immense expectations presented in the proposed rule. While Network practices currently document most, if not all, of the CDEs required by the RO Model, the specifications for reporting to CMS are very detailed and the EMR vendors will need time to develop new computer code, test changes, and ultimately deliver new software to providers, who will in turn need to be trained on the program before testing it within their systems and retooling their workflows. Until this is established, CDE reporting will be a highly manual process requiring additional time and resources. For example, each practice will need to track, enter, and upload CDEs on an Excel template created by CMS. The CDEs need to be translated to code and treatment phases need to be entered separately. Delaying this requirement will give providers time to stand up the Model without substantially increasing burden and costs on the practice.

<u>Operational Burden</u>

In the CY 22 OPPS proposed rule, CMS estimates the burden for collecting and reporting quality measures and clinical data for the RO Model is approximately $1,845 per entity per year based on 2020 wages. The Network believes not only has CMS underestimated this reporting burden, but moreover, CMS has failed to consider the resources needed to implement changes to provider billing and revenue cycle operations. Given the intricacy outlined below, we estimate each Network practice participating in the Model will need one full-time staff person dedicated to ensuring billing and coding is done correctly.

The RO Model is highly complex, making it very difficult to effectively utilize our existing automated systems. Until this is functionality is developed, the Model will require manual intervention to track the episode start date for eligible participants, to track treatment progression through the initial 90-day period and subsequent clean period, and to

accumulate and bill the "no-pay" CPT codes. Changes in treatment, diagnosis, etc. may result in revisions to the billing process. This complexity is heightened for practices who perform only the technical or only the professional component; in many instances, this will require cumbersome manual coordination with unaffiliated practices on disparate systems. Practices with multiple locations, where some sites are participating in the Model and others are not, will experience additional complications.

Relatedly, The Network highlighted the complexity of coordinating with Medigap plans, who operate on a fee-for-service basis, in our comments on the RO Model proposed rule in 2019. Medigap plans comprise 20% of revenue and practices will have to figure out how the process works for each individual plan. We are still awaiting guidance on how to bill secondary insurers, whether they will be prepared to process RO Model secondary claims, and how the withholds and beneficiary coinsurance will work for Medicare beneficiaries with Medigap or other supplemental coverage. Further guidance is also needed regarding when patient cost sharing must be collected as well as the reconciliation process. **Again, it takes time and resources to change systems and workflow, so we strongly urge CMS to provide more detailed billing guidance.**

The RO Model's complexity is at odds with CMMI's stated goal of developing new models aimed at improving patient care, lowering costs, and better aligning payment systems to promote patient-centered practices. We also caution CMS that this burden will likely be higher on smaller practices who may not have the administrative and financial resources to assume the workload and risk associated with the Model.

Extreme and Uncontrollable Circumstances

CMS is proposing to adopt an Extreme and Uncontrollable Circumstances (EUC) policy, defined as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale. If CMS declares an EUC for a geographic region, CMS may: (1) amend the Model performance period; (2) eliminate or delay certain reporting requirements for RO participants; and (3) amend the RO Model's pricing methodology. The Network supports this proposal and encourages CMS to consider whether the COVID-19 public health emergency would qualify as an EUC to provide temporary flexibility to participating practices.

Over the past 18 months, community cancer clinics have demonstrated tremendous resilience and value in helping patients receive care close to home, which has allowed hospitals to maintain capacity to treat patients with COVID-19. Our practices rapidly adopted telehealth to see patients virtually and adapted workflows to allow more staff to work from home. While patient volumes may be returning, practices continue to face new hurdles, such as the more contagious Delta variant, vaccination policies, and staffing shortages. Transitioning to a new payment system under the RO Model adds another layer of obstacles. Given the COVID-19 pandemic's unprecedented and persistent challenges, **The Network urges CMS to re-examine the RO Model's payment reductions and reporting requirements through this lens.**

Model Overlap

The Network remains dedicated to the pursuit of value-based care to both improve quality and lower costs but cautions that details matter. Unnecessary complexity and administrative burden have the potential to hinder practice transformation. This complexity is compounded when practices are forced to participate in multiple APMs. According to our internal analysis, we anticipate approximately 22% of RO Model patients will also be participating in the OCM. We also note that CMMI has previously proposed mandatory models to test drug payments that would encompass a large majority of oncology practices across the country. The Network is encouraged by CMMI's recognition of this dynamic in its August 6 blogpost in *Health Affairs*, which states, "Offering too many models is overly complex, particularly when models overlap." We agree that that overlapping models creates difficulty in properly evaluating model success and

may dilute the strength of model incentives. We caution that participating in multiple overlapping models will further increase practice burden and could impact access to care. **As the nation's largest network of community-based oncology practices, many of whom are participating in one or more APMs, we offer our expertise to CMS to help achieve its vision of launching fewer models and scaling what works.**

We welcome the opportunity to discuss the issues outlined above and other critical issues impacting community cancer care with you and your staff. Should you have any questions, please contact Ben Jones, Vice President of Government Relations and Public Policy, at Ben.Jones@usoncology.com.

Sincerely,

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Chief Radiation Oncology Officer
The US Oncology Network