ASTRO
TARGETING CANCER CARE

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July 22, 2020

Brad Smith
Deputy Administrator and Director
Center for Medicare and Medicaid Innovation
2810 Lord Baltimore Drive
Windsor Mill, MD 21244

Dear Mr. Smith,

The American Society for Radiation Oncology (ASTRO)[1] greatly appreciates the opportunity to engage with the Center for Medicare and Medicaid Innovation (CMMI) on the development of an alternative payment model for radiation oncology. Further, ASTRO appreciates the work of CMMI and the Centers for Medicare and Medicaid Services (CMS) to provide regulatory flexibilities in response the COVID-19 Public Health Emergency (PHE). In the context of the PHE, ASTRO continues to look forward to the publication of the "Specialty Care Models to Improve Quality of Care and Reduce Expenditures" final rule with the acceptance of critical recommendations made by ASTRO in our Sept. 16, 2019 comment letter, and we seek to engage CMMI to address our serious concerns that COVID-19 will have a significant impact on the ability of practices to participate in the model. As we continue to assess the relationship of COVID-19 and the RO Model, we have identified additional concerns about mandatory participation, quality reporting, the trend factor and case mix methodology that require modifications to account for the impact of the PHE.

<u>COVID-19 Impact</u>

When the RO Model proposed rule was released in July 2019, COVID-19 was not considered by the Agency nor the radiation oncology community. Much has changed over the past several months, and while ASTRO strongly supports efforts to continue the transition from fee-for-service payment to value-based payment, it cannot be done without considering the ongoing impact of COVID-19 on radiation oncology practices.

Radiation oncology practices across the country have found themselves in the tenuous position of continuing to provide cancer treatment during the greatest pandemic the United States has experienced in generations. While many cancer patients have been able to make the uncomfortable decision to delay care, others have not. Radiation oncology practices have

[1] *ASTRO members are medical professionals, who practice at hospitals and cancer treatment centers in the United States and around the globe and make up the radiation therapy treatment teams that are critical in the fight against cancer. These teams often include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers, and treat more than one million cancer patients each year. We believe this multi-disciplinary membership makes us uniquely qualified to provide input on the inherently complex issues related to Medicare payment policy and coding for radiation oncology services.*

demonstrated remarkable resiliency and continued to treat the most vulnerable and complex cancer patients throughout the COVID-19 PHE. They have modified their practices to ensure that patients and care teams are protected from COVID-19 exposure, these protections include patient and staff wellness screenings; purchases of PPE and other protective equipment; more rigorous sanitation of treatment rooms in between treatments; and changes to clinician and staff schedules to ensure practice coverage should a member of the team become ill. These efforts come at a significant financial cost, not to mention the emotional toll of being an essential health care worker.

ASTRO believes the significant impact of COVID-19 on radiation oncology practices necessitates further modifications to the RO Model before it is finalized. In particular, we urge the Agency to reconsider requiring participation in the model. Health care and radiation oncology care has been upended by COVID-19 and this is certainly not the environment to mandate participation in a payment model that has not been tested. At minimum, the Agency should dramatically scale back the number of required participants and allow an unlimited number of radiation oncology practices to voluntarily participate in the RO Model.

Radiation oncology practices will need time to consider and implement model requirements in order to ensure successful participation. This is particularly critical as many are still working to achieve a new normal in response to COVID-19, as hotspots continue to impact communities unevenly across the country and are likely to continue to do so into 2021. Given these challenges and uncertainties, **ASTRO recommends providing a minimum of 6 months between publication of the final rule and the official RO model launch. Further, ASTRO recommends a phased in approach that would allow practices to ramp up over a period of time at their own pace while meeting predetermined benchmarks within a set amount of time.**

According to an ASTRO survey of radiation oncology medical directors, radiation oncology practices are experiencing significant declines in revenue, with the majority of practices reporting declines between 10-30% during the PHE.[2] The RO Model proposes to include significant discount factor cuts (4% off the PC and 5% off the TC), in addition to withholds for incorrect payments and quality measures performance. These are significant cuts that will be layered on to the financial impact of COVID-19. **In order to remain financially viable and capable of delivering cancer care to their communities, ASTRO believes the Agency should permanently reduce the discount factors and defer the withholds until at least year two of the model demonstration.** Phasing in the withholds no sooner than the second performance period will ensure that participating practices have the cash flow necessary to adapt to the RO Model quality reporting, claims adjudication, and revenue management requirements while (hopefully) recovering financially post-COVID-19. **Further, the Agency must reverse its proposal to waive the 5% APM incentive payment to the technical component while still**

[2] *COVID-19's Impact on Radiation Oncology: Initial Results of a Nationwide Physician Survey.* ASTRO 5/20/20

applying the 5% discount on the technical component as the combination has the potential to devastate freestanding practices and limit access to care.

While we are hopeful that the PHE will end in the near future, we are concerned that implementing the RO Model during the midst of the pandemic will be too much for many practices to bear due to the fact that the Model requires EHR upgrades, new coding and claims reporting requirements, as well as quality measure data reporting, clinical data elements collection, and compliance monitoring that will take a significant amount of clinical and administrative time. This concern is particularly acute given the massive declines in practice revenues and volumes, which have led 58% percent of ASTRO survey respondents to report lay-offs and furloughs due to the PHE. Among those respondents reporting layoffs, 20% report scaling back experienced physicians and 39% report reductions in administrative staff, both of which would be heavily involved in RO model implementation.

It is even more important now for CMS to align quality reporting in the RO Model with other CMS reporting programs such as the Merit Based Incentive Payment System (MIPS) and Oncology Care Model (OCM) and minimize mandatory reporting of quality measures. Practices are facing significant clinical, operational, and financial burdens due to the PHE. **Alignment with existing reporting requirements and minimizing mandatory data elements reporting will help support practices as they transition to value-based care.**

Additionally, the RO Model proposes clinical data collection for prostate, breast, lung, bone metastases, as well as the cost of equipment and frequency of treatment for all patients. This requirement is particularly burdensome given that there are no existing EHR systems in place that allow for seamless transmission of the data. Much of it would have to be performed manually until vendors are able to develop and implement the software required for this type of data transmission. ASTRO has been actively working with the MITRE Corporation on a Common Oncology Coding Extension (CODEx) project that will allow for the development of a minimum oncology code data elements (mCODE) specific to radiation oncology services. Once that is developed, vendors will need time to implement it into existing EHR systems that are used by radiation oncology practices. It could take up to 8 months to develop the standards and then another 6-12 months to implement such a system, maybe longer given the strains that vendors have felt as they have also had to furlough staff and make budget cuts due to COVID-19.

Finally, we believe that the monitoring requirements associated with the RO Model should be reconsidered. Given that CMS has had to cut back on on-site audits for OCM practices due to COVID-19 and the continued uncertainty regarding when the PHE will end, a more simplified approach should be considered. **Accreditation would provide stability and predictability for practices in the RO Model.** Additionally, it will ensure that practices participating in the model have met a specific level of quality in the delivery of care, while at the same time reducing the need for on-site visits saving CMS staff time and resources.

Trend Factor

As referenced above, 85% of respondents to ASTRO's COVID-19 impact survey indicated a decline in patient volumes. On average, patient volumes were down by one-third during the initial onset of the PHE, and a recent update to the survey indicate that declines persist, with practices reporting patient volumes still down approximately 30% from pre-pandemic levels. The declines were due to treatment delays, as well as declines in referrals. ASTRO is concerned that the decline in 2020 patient volumes will have a negative effect on the calculation of the RO Model Trend Factor. According to the proposed rule, the Trend Factor calculation is designed to account for trends in payment rates and volumes for radiation therapy services outside of the Model under the Hospital Outpatient Prospective Payment System and the Medicare Physician Fee Schedule. The calculation involves the average number of times each HCPCS code was furnished for the most recent calendar year with complete data.

Additionally, ASTRO worked with European colleagues to develop consensus based guidance for head and neck[3] and lung cancer[4] patients to recognize this unique time of limited resources and heightened risk for patients and staff. These recommendations were developed in the context of this novel medical ethics dilemma: urgency to treat vs risk of infection. These recommendations were believed to be needed based on the urgency for these diseases to be treated, as compared to some other more indolent diseases that could be delayed. These recommendations do not carry with them the same evidence-base as clinical practice guidelines and are not the standard of care in the absence of such an unprecedented PHE. This guidance combined with decisions to delay treatment for breast and prostate cancer demonstrate that utilization data during the PHE represents an approach to care that would not be carried out under normal circumstances. As such, data related to the provision of care, during the PHE, should not be used for benchmarks outside of the PHE.

Based on the proposed rule, 2020 utilization data will be used to inform the trend factor in 2023. Use of 2020 utilization data as part of the RO Model Trend Factor would be inappropriate given the significant declines in patient volume due to COVID-19. **ASTRO urges the Agency to modify the Trend Factor methodology in 2023 to exclude 2020 data points. Instead, 2019 data should be used, as it is a more accurate representation of radiation therapy service utilization.**

Case Mix

The RO Model case mix methodology is based on pre-COVID-19 case mix adjustment variables, including cancer type; age; sex; presence of a major procedure; death during the first 30 days, second 30 days or last 30 days of the episode; and presence of chemotherapy. If the model is implemented in 2021, the case mix variables used to inform the payment rates are likely to be based on 2016-2018 data. According to the proposed rule, the case mix data points will be

[3] https://www.redjournal.org/article/S0360-3016(20)31034-8/fulltext
[4] https://www.sciencedirect.com/science/article/pii/S0167814020301821

updated each performance year (PY) to recognize a rolling three year average, thus 2022 (PY2) case mix methodology will be based on 2017-2019 data, 2023 (PY3) on 2018-2020, and so on.

Due to COVID-19, many patients have delayed diagnostic tests and cancer treatment, thus making the case mix variables a potentially unreliable predictor of fee-for-service costs post-COVID-19. Delayed testing and treatment are expected to result in patients presenting with advanced stage disease requiring more complex and expensive treatment in the future[5]. The impact of COVID-19 on practice specific patient case mix will not appear until 2021, because of delays in data collection associated with payment models those data points would not be folded into the case mix methodology until PY4 (2024).

ASTRO urges the Agency to establish a COVID-19 case mix adjustment to account for delays in care and the resulting advance stage disease and complexity of patient cases that will present during the demonstration period. This adjustment, which should be proposed and reviewed by the radiation oncology community, should be applied to the first through third performance periods to ensure that practice payment rates adequately recognize the additional costs necessary to care for this patient population. In the absence of such an adjustment the historical practice case mix methodology would be inadequate and jeopardize the financial stability of those practices participating in the model, penalizing those caring for patients with more advanced disease while recovering from significant 2020 revenue losses (10-30%, on average, according to ASTRO survey) all of which are due to the COVID-19 PHE.

Again, ASTRO strongly supports efforts to transition the field of radiation oncology from fee-for-service to value-based payment and the promise of payment stability associated with a more balanced RO Model is more important than ever. However, CMS and the radiation oncology community must work together to further modify the RO model to account for the unprecedented impact of COVID-19. We look forward to engaging with the Agency to best determine how to address the impact of the PHE so that the model can be successfully implemented. Thank you for the opportunity to raise these issues, please contact Anne Hubbard, Director of Health Policy, at 703-839-7394 or Anne.Hubbard@ASTRO.org if you have any questions.

Sincerely,

Laura Thevenot

Laura I. Thevenot
Chief Executive Officer

[5] *Sharpless, Norman E., COVID-19 and Cancer. Science. 19 June 2020: Vol. 368, Issue 6497, pp. 1290*

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