ASTRO
TARGETING CANCER CARE

251 18th St. South, 8th Floor
Arlington, VA 22202

Main: 703.502.1550 · Fax: 703.502.7852
www.astro.org · www.rtanswers.org

September 9, 2021

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

Dear Administrator Brooks-LaSure:

Two presidential administrations and six years ago, the American Society for Radiation Oncology[1] (ASTRO) initiated thoughtful and collaborative discussions with the Centers for Medicaid and Medicare Innovation Center (CMMI) on the development of an alternative payment model for the field of radiation oncology. ASTRO entered into these discussions because we believed that:

1. Radiation oncologists should have the opportunity to fully participate in the Quality Payment Program and be rewarded for participation and performance in initiatives that improve the value of health care for patients.
2. An alternative payment model for radiation oncology should ensure fair, predictable payment for the radiation oncologist in both hospital and freestanding cancer clinics to protect cancer patients' access to care across all settings.
3. An alternative payment model should incentivize the appropriate use of cancer treatments that result in the highest quality of care and best patient outcomes.

Early in the process, the Centers for Medicare and Medicaid Services (CMS) recognized that radiation oncology faced payment instability due to its reliance on significant capital costs. According to the November 2017 Report to Congress, the Agency believed that an alternative payment model could establish long warranted rate stability to ensure continued access to this vital and high-value form of cancer care:

> "A potential model could also test more stable pricing for freestanding radiation therapy centers paid under the Medicare Physician Fee Schedule… CMS faces certain challenges in determining accurate prices for services that involve expensive capital equipment. Consequently, PFS rates for services involving external beam radiation have fluctuated over the last decade. Under an episode payment model, more stable prices for radiation

[1] ASTRO members are medical professionals practicing at hospitals and cancer treatment centers in the United States and around the globe. They make up the radiation treatment teams that are critical in the fight against cancer. These teams include radiation oncologists, medical physicists, medical dosimetrists, radiation therapists, oncology nurses, nutritionists and social workers. They 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.

> therapy services could be tested to determine if they reduce expenditures while maintaining or enhancing quality of care."[2]

Since then, however, these goals and aspirations of payment stability have been cast aside in favor of significant payment cuts, all the result of actuarial determinations that have been made with little transparency and no discussion. Despite the disappointments that CMS has laid at our feet since the issuance of the proposed rule in July 2019, we will continue to push for a payment model that is fair and equitable. We believe in value-based payment and recognize that Fee-for-Service (FFS) is no longer a viable option for radiation oncology.

The CMS RO Model as presently structured is inconsistent with President Biden's commitment to "Ending Cancer as We Know It". As the world's premier radiation oncology society, with more than 10,000 members, we are aligned in our commitment to the goal of cancer eradication. However, that goal cannot be achieved through the implementation of payment cuts and administrative reporting requirements, like those included in the RO Model, that only serve to undermine the physicians, nurses, physicists, radiation therapists, dosimetrists and other healthcare professionals who are on the front lines working toward achieving the goal of ending cancer every day.

ASTRO noted with great interest your Aug. 6 *Health Affairs* blog and vision for the next 10 years of the Innovation Center, particularly point 6: "Innovation Center models can define success as encouraging lasting transformation and a broader array of quality investments, rather than focusing solely on each individual model's cost and quality improvements."[3] We agree with this vision but believe the RO Model, as it is currently crafted, will fail to realize it. The radiation oncology community believes that the RO Model inappropriately prioritizes model savings over health care transformation. Radiation oncology episode-based payment bundles alone would be highly transformative, in terms of quality and cost, but CMS' excessive emphasis on mandating savings has marred and corrupted this promising approach. It's not too late for the Agency to recognize this flaw and make corrections.

In this letter, we urge CMS to make the following priority modifications to the RO Model:

- Establish rate stability through the application of a discount factor set at 3% or less and address the impact of continued MPFS payment cuts on RO Model participants.
- Recognize the significant impact that COVID-19 has had on participating practices through the establishment of a COVID-19 adjustment.
- Eliminate the unnecessary Track One and Track Two proposal, as well as other barriers to Advanced APM status, including the waiver on the application of the 5% bonus on freestanding technical payments.

---

[2] United States Department of Health and Human Services, "Report to Congress: Episodic Alternative Payment Model for Radiation Therapy Services," November 2017.

[3] Brooks-LaSure, Chiquita, Elizabeth Fowler, Meena Seshamani, and Daniel Tsai. "Innovation at the Centers for Medicare and Medicaid Services: A Vision for the Next 10 Years." HealthAffairs. August 12, 2021. https://www.healthaffairs.org/do/10.1377/hblog20210812.211558/full/

- Address the impact of the RO Model on rural practices and those serving disadvantaged practices through the establishment of a Health Equity Achievement in Radiation Therapy payment to cover wraparound services.

In December of the 2020, Congress delayed the start of the RO Model until Jan. 1, 2022, so the agency could provide practices more time to prepare and work with the community to improve the model. On December 18, 2020, 14 bipartisan members of the House of Representatives wrote CMS to express concerns that the RO Model had not made substantive improvements to the model's payment methodology[4]. The Representatives said, "the Model is still very complicated and provides little opportunity for providers to receive incentive payments for achieving the model's goals to assure quality outcomes for patients. ***We are concerned that the intensity of the payment cuts are so significant that it could have the unintended effect of reducing quality.***" ASTRO believes the RO Model minor revisions made by CMS fail to respond to these concerns.

Discount Factor Cuts

In the 2022 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule, CMS proposes a .25 percentage point reduction in the discount factor on both the professional component (PC) and technical component (TC). This reduces the RO Model discount from 3.75% on the PC and 4.75% on the TC to 3.50% and 4.50% respectively.

According to the Agency, the removal of brachytherapy as a modality of treatment and liver as an included disease site in the RO Model, enables it to lower the discount factor without increasing the size of the RO Model (i.e. requiring more practices to participate) in the mandatory demonstration.

CMS anticipates that based on this proposal it will be able to save 3.2%, or $160 million in Medicare FFS spending. However, we believe the Agency has failed to account for the continued decline in Medicare Physician Fee Schedule (MPFS) rates that flow through the RO Model payment methodology as part of the Trend Factor.

In the 2022 MPFS proposed rule, CMS is proposing cuts of 8.75% across all radiation oncology services, due to the proposed change in Clinical Labor Pricing Inputs and the expiration of the Consolidated Appropriations Act (CCA), which equates to a cut of 3.75% to the Conversion Factor. These significant cuts come at a time when practices are still reeling from patient volume declines related to COVID-19, which reduced revenues in 2020 by 8%, and another wave of COVID-19 infections leading hospitals to cancel elective procedures. If the MPFS cuts are instituted, radiation oncology will have experienced a cumulative 10-year reduction in MPFS payments of 25%.

[4] Congress of the United States, "Concerns regarding the current Framework of the finalized Radiation Oncology Alternative Payment Model." December 18, 2020.
https://www.astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/RadiationOncologyModelLetter.pdf

The discount factors combined with continued declines in MPFS payment rates equate to a total of $300 million in payment cuts for the specialty. Reductions of this magnitude will put many practices in financial jeopardy, preventing them from providing care not only to Medicare FFS beneficiaries, but entire communities, as many will be forced to cut back services and others may not be able to keep their doors open. CMS has done virtually nothing to address concerns that the RO Model's payment methodology is likely to significantly harm those practices that are already operating very efficiently, those with higher proportions of Medicare FFS beneficiaries, or those that serve rural or socioeconomically disadvantaged populations requiring greater resource expenditures. These practices, operating on thin margins, could be forced to take drastic steps to continue serving patients.

CMS has also neglected to address concerns regarding the significant investments required to operate radiation oncology clinics. The discount factor and the punitive payment methodology do not recognize the multimillion investment in capital equipment and ongoing support of highly skilled staff necessary to operate a clinic. Practices will struggle to invest in the human and technological infrastructure to provide high quality, state-of-the-art care.

ASTRO continues to recommend that the Agency set the discounts at 3% or less. Reducing these cuts to 3% would still generate significant savings for Medicare and better align the RO Model's discount factors with those of other APMs. Additionally, CMS must act to address the continued declines in the MPFS payment rates. Continued MPFS rate declines will exacerbate rate instability issues, putting practices that are compelled to participate in the RO Model in double jeopardy, as they will be subjected not only to the draconian discount factors, but also the declines in MPFS rates, preventing them from successful participation.

Brachytherapy Exclusion

In the 2022 HOPPS proposed rule, CMS is proposing to omit brachytherapy, one of the most high-value modalities of treatment from the RO Model. ASTRO is surprised by this proposal, as neither ASTRO nor the American Brachytherapy Society advocated for brachytherapy's removal. However, multiple times we have urged CMS to ensure that the RO Model payment rates adequately reflect guideline concordant care, which frequently involves external beam radiation therapy (EBRT) and brachytherapy. In previous comment letters and other correspondence, ASTRO has supplied the Agency with guidance including common scenarios to consider for episode development and adequate payment.

Given the RO Model's limitations and inability to account for the added expense of brachytherapy when combined with EBRT, it is reasonable to exclude brachytherapy from the RO Model. However, this does not address the overarching concerns that ASTRO and others have expressed regarding the inadequate reimbursement for brachytherapy services that have created access to care issues for this particular modality for years. The removal of brachytherapy effectively removes almost all reconciliation related activity from the RO Model. If the Agency pursues the removal of brachytherapy, ASTRO urges CMS to also remove the incorrect payment withhold from the payment methodology.

Participant Exclusions

In the 2020 Specialty Care Model final rule, CMS excluded radiation oncology practices in Maryland and Vermont, as well as any practice classified as an ambulatory surgical center, Critical Access Hospital (CAH) or Prospective Payment System (PPS)-Exempt cancer hospital, or participants in or as identified by CMS as eligible to participate in the Pennsylvania Rural Health Model (PARHM).

In the 2021 OPPS proposed rule, CMS is proposing to modify the PAHRM exclusion by only excluding those practices that are participating in PARHM, rather than those that are eligible to participate but choose not to participate. CMS justifies this by stating that those participating in PAHRM receive global budgets that include payment for RT services and would therefore overlap with the RO Model payment. Those that are eligible but not participating in PARHM are not subject to this potential overlap in payment; therefore, CMS is proposing that they be mandated to participate in the RO Model.

CMS is also proposing to update the exclusions criteria to exclude Community Health Access and Rural Transformation (CHART) Model participants from participating in the RO Model. The Agency justifies this exclusion by stating that these hospitals receive prospectively paid capitated payments that are not retrospectively reconciled based on experience, therefore also subject to double payment for RT services.

ASTRO opposes the inclusion of any new PGPs or HOPDs, including PARHM eligible groups, in the RO Model. We remain concerned that the model is untested and presents a significant financial and administrative burden on those selected to participate. ASTRO has always advocated for voluntary participation, particularly in the initial implementation phase. For these reasons, we do not believe it is appropriate to include PARHM eligible practices in the RO Model. **However, we do support CMS' proposal to exclude CHART Model participants.**

Participation Preparation

In the 2022 HOPPS proposed rule, CMS states that it plans to launch the RO Model on January 1, 2022. This is less than six months away from the time that the proposed rule was issued and will be a mere two months after publication of the final rule. In the proposed rule, CMS states that it will not be able to provide Case Mix or Historical Experience Adjustment data inputs to participating practices until after the final rule is issued. The data used to inform these inputs is 2017-2019. This is the same data included in the data file published with the proposed rule.

CMS must supply these data inputs immediately. It is unfair that the Agency is withholding this important information that could help RO Model participants better understand the financial implications of participating in the program. This lack of transparency is frustrating, particularly in light of recent pledges by CMS in the *Health Affairs* blog of "greater transparency and accessibility to Innovation Center data.". Additionally, CMS has issued its payment methodology tool for practices to use, but without these data inputs, that tool is useless. **CMS must do more than talk about being transparent and provide the data.**

COVID-19 Public Health Emergency

Trend Factor Modification

In the 2022 HOPPS proposed rule, CMS proposes to modify the volume component of the trend factor to address significant utilization shifts. According to the proposal, when RO Model participants experience nation-wide aggregate-level disruptions to their service utilization that cause the trend factor (specific to a cancer type and component) for the upcoming PY to increase or decrease by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payments are held constant with the previous CY, the Agency may modify the trend factor calculation for the PC and/or TC of an included cancer type.

ASTRO agrees with CMS' proposal to revise the volume component associated with the trend factor to address fluctuations in utilization due to national disruptions in care, such as the COVID-19 public health emergency (PHE). However, we do not agree with the application of a 10% threshold. CMS should simply not use the affected year's data and apply the most recent unaffected years data to the volume component when calculating the trend factor. During the PHE, treatments have been interrupted or truncated prior to completion due to COVID infection and/or local quarantine requirements for patients, family caregivers, or clinic staff; the full extent of these unanticipated disruptions on clinical care is impossible to determine. All such effects would likely generate an artificial underestimate of the true cost of care under ordinary circumstances. By resetting the volume to the most recent unaffected year's data, CMS is preserving the opportunity to accurately compare RO Model participants with non-RO Model participants. Otherwise, those practicing outside of the RO Model will continue to utilize services as they normally would once the disruptive event has passed, while those inside the model are subjected to the constraints of the lower volumes associated with the disruptive event.

Additionally, ASTRO appreciates that CMS has recognized that the trend factor could create significant instability, however, instability is not limited to the volume component of the methodology. Because the trend factor is also reliant on yearly MPFS and HOPPS updates, payment instability in the RO Model can also be attributed to significant payment shifts in those existing payment systems. This is the reality in 2022, as radiation oncology faces an 8.75% decrease under the MPFS, with some services down as much as 22%. **ASTRO urges CMS to address rate instability through the application of a guard rail on the trend factor to prevent significant shifts in payment under the RO Model from year to year. A guardrail of +/-2% would help establish rate stability for those compelled to participate.**

<u>Case Mix Adjustment</u>

In the 2022 HOPPS proposed rule, CMS states that it is analyzing whether the COVID-19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historic levels. CMS is considering removal of 2020 data from the calculation of any applicable baseline period or trend factor. However, the Agency is not considering the exclusion of 2020 from case mix adjustment at this time, because the case mix episodes are weighted equally, and the case mix adjustment does not rely on the volume of RT services delivered. The Agency is seeking comments on this approach to addressing utilization during the public health emergency.

ASTRO recognizes that case mix is weighted equally for the three-year rolling period that is included in the payment methodology. Additionally, we understand that utilization is not a component in the case mix methodology. However, we are concerned that the six factors included in case mix: cancer type,

age, sex, presence of major procedure, death during episode, presence of chemotherapy, do not recognize the acuity of patient care that may be required as patients, who have delayed diagnostic services and treatment due to COVID-19, present with more advanced stage disease, which requires more expensive radiation therapy treatment.

Because historical experience adjustment is based on 2017-2019 data and stays constant throughout the duration of the demonstration period, the additional cost associated with delivering more expensive treatment for advanced disease due to COVID-19 won't be captured in that component of the payment methodology. CMS must recognize and address this issue.

A COVID-19 adjustment needs to be applied to the case mix to address the increased cost of care that many of patients now require. Given that the case mix changes from year to year, it would seem this would be the most appropriate place to apply an adjustment based on the increased cost of care that practices are experiencing.

Advanced APM and MIPS-APM Status

In the 2022 HOPPS proposed rule, CMS proposes to establish that those Professional and Dual participants who meet RO Model requirements, including use of CEHRT, and who are eligible clinicians on a participation list, will fall into a category called "Track One" of the RO Model. CMS proposes to define "Track One" as an Advanced APM and MIPS APM track for Dual and Professional participants that use CEHRT.

RO Model participants in Track One will be considered 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 and can report to MIPS using reporting options applicable to MIPS APM participants.

If Professional or Dual participants fail to meet any of the RO Model requirements, which includes CEHRT, they will be moved to a proposed "Track Two" category. "Track Two" means an APM for Professional and Dual Participants, who do not meet the RO Model requirements and for all Technical participants. Track Two participants are not considered to be either Advanced APM or MIPS APM participants. Therefore, CMS will not make QP determinations for eligible clinicians on the RO Model participation list for Track Two.

CMS should abandon the two-track approach, which is yet another example demonstrating the punitive nature of the RO Model, as the Agency takes great pains to prevent practices from accessing the already-limited upside for participating in an APM. It is curious that CMS has sought to make CEHRT the qualifier for Track One status. In previous comment letters, ASTRO has pointed out the fact that small radiation oncology practices and those in rural settings have been exempt from the CEHRT requirements under MIPS. We have urged CMS to extend that exemption to practices meeting the same criteria under the RO Model. Otherwise, these practices are deemed MIPS APMs and ineligible for the advanced APM bonus, despite being compelled to participate in the RO Model and its excessive payment cuts and administrative burdens.

These are the same practices that see higher portions of Medicare FFS beneficiaries and typically lack the capital funding necessary to invest in newer, more efficient technology, as well as the upgrades in EHR systems for quality measures reporting. It's as if CMS is purposely looking for ways to prevent RO Model participants, particularly the more disadvantaged practices, from achieving the 5% Advanced APM bonus. This may be why the Agency has adjusted its Advanced APM QP status estimate from 82% of all RO Model participants to 80% of all RO Model participants. Two percent may seem like a small number but for those practices unable to attain advance APM status it will be devastating, as many of them will be left with fewer resources and will be unable to care for patients as a result of this very short-sighted proposal.

Additionally, if practices are deemed Track Two participants, how is it that CMS can then determine that they are not MIPS APMs? According to 42 CFR Sec. 414.1370, MIPS APMs criteria include the following:

1) APM entities participate in the APM under an agreement with CMS or through a law or regulation;
2) The APM is designed such that APM entities participating in the APM include at least one MIPS eligible clinician on a Participant List;
3) The APM bases payment on quality measures and cost/utilization; and
4) The APM is neither an APM for which the first performance year begins after the first day of the MIPS performance period for the year or an APM in final year of operation for which the APM scoring standard is impracticable.

Since the RO Model is a CMMI designated Advanced APM, then MIPS APM Status is designated for those practices that don't meet the Advanced APM or QP standards. Again, why is CMS proposing the Track One and Track Two Categories? This unnecessary, pernicious approach make the process of achieving Advanced APM status and even MIPS APM status even more difficult for RO Model participants.

<u>Monitoring Requirements</u>

CMS states in the 2022 HOPPS proposed rule that "any failure, however minor, to comply with the RO Model Requirements set forth at sec. 512.220(a)(2) will have an impact on whether a RO Model participant is in Track One versus Track Two." Section 512.220(a)(2) contains the following monitoring requirements:

1) discuss goals of care with each Medicare beneficiary before initiating treatment and communicate to the beneficiary whether the treatment intent is curative or palliative;

2) adhere to nationally recognized, evidence-based treatment guidelines when appropriate in treating Medicare beneficiaries or document in the medical record the rationale for the departure from these guidelines;

3) assess the Medicare beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnosis;

4) assess the Medicare beneficiaries' performance status as a quantitative measure determined by the physician;

5) send a treatment summary to each Medicare beneficiary's referring physician within three months of the end of treatment to coordinate care;

6) discuss with each Medicare beneficiary prior to treatment delivery his or her inclusion in and cost-sharing responsibilities; and

7) perform and document Peer Review for 50 percent of new patients in performance year 1, 55 percent of new patients in performance year 2, 60 percent of new patients in performance year 3, 65 percent of patients in performance year 4, and 70 percent of patients in performance year 5, preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within two weeks of starting treatment.

ASTRO is very disappointed in CMS' decision to use such punitive language associated with the RO Model monitoring requirements. This language and approach are bureaucracy at its worst and should be revised. We have asked the Agency multiple times to share with the radiation oncology community specifics on how to provide evidence of compliance with these requirements. This is particularly concerning given that EHRs currently don't collect this data.

According to the proposed rule, CMS is seeking input on whether some of the requirements associated with section 512.220(a)(2) should be modified and whether the RO Model can meaningfully improve the quality of care if any of the requirements are modified. 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, ASTRO 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. This is just another unfunded mandate and an administrative burden for practices. ASTRO remains concerned regarding the related financial costs that participants will incur due to forced participation in the RO Model. Vendors will shift costs to radiation oncology clinics, which must hire staff to collect and report on these requirements, adding significant financial burden associated with mandatory RO Model participation.

Given that the CMS has yet to provide additional clarifying guidance regarding how the Agency expects practices to collect and report on this data, we recommend 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, which is particularly egregious considering that ASTRO has raised it numerous times over the last two years.

<u>Waiver of 5% bonus on Technical Services</u>

In the 2020 RO Model final rule, CMMI approved a waiver that would prevent freestanding practices from recognizing the 5% Advanced APM bonus for technical payments, as prescribed by the Medicare

Access and CHIP Reauthorization Act (MACRA). ASTRO continues to believe that this waiver is arbitrary and capricious, and a clear violation of the spirit of MACRA. This waiver further limits community-based clinics, particularly those who provide services to underserved populations, from investing in the technology necessary to provide high quality care.

The 5% Advanced APM bonus is not only an incentive to participate in the model, but is also designed to support practice transformation essential for meaningful APM participation. The RO Model participation requirements establish new, unreimbursed practice expenses that would normally be paid from technical fee revenue. **Unless the 5% bonus is applied to both the professional AND technical charges for freestanding participants, those practices will be at a distinct disadvantage and unable to achieve true practice transformation.**

Cost of Compliance

In the 2022 HOPPS Proposed Rule, CMS estimates that the burden for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which the Agency estimates to be approximately $1,845 per entity per year based on 2020 wages. Over 950 participants, this estimate equates to $922,500 per year or $4.6 million over the five-year duration of the program.

ASTRO is deeply concerned that CMS has woefully underestimated the cost of collecting and reporting quality measures and clinical data elements. Several hospital systems that will participate in the RO Model have performed their own initial analysis and the burden anticipated by those practices is significantly higher than CMS' estimate.

One mid-western hospital system has reported that even though all eight regions within the health system use an existing radiation oncology EHR system, only a couple are using it to also document care. Those systems that are using the EHR system to document care will need to implement various software product upgrades to support the higher level CEHRT requirements. The cost of which is an estimated $1.74 million for all eight regions. This does not include the cost associated with staff time or the ramp up time necessary to train and operationalize these new systems.

Additionally, a large academic medical center with OCM experience, has reported that the cost of compliance is three- to four-times the anticipated cost of the 2% withhold. Effectively CMS has put practices in a position of deciding whether they want to make the financial investment into reporting quality measures and CDEs rather than working with practices on meaningful compliance. This same group reports that OCM compliance relies heavily on trained cancer registrars, one per 1,000-1,300 patients, to extract data, which is then manually uploaded.

CMS has yet to address the concerns that ASTRO and other radiation oncology stakeholders have raised regarding the investment required to stand up and operationalize reporting systems. **We continue to believe that the Agency is moving too quickly and will put many practices in financial jeopardy, as they try to comply with these overly expensive and time-consuming burdens. We urge CMS to delay these requirements for two-years and allow time for reconsideration and more stakeholder feedback that may yield a better plan moving forward.**

RO Model Billing Requirements – Potential OPPS Rate Setting Impact

ASTRO asks CMS to clarify how the RO model billing requirements will impact the data CMS uses for rate setting in the OPPS. In an August 24th RO Model Billing Webinar, CMS instructed hospital RO model participants to "verify that RO Model HCPCS codes do not have a charge less than the fee amount" for the beginning and end of episode claims for the technical component[5]. Additionally, RO model participants were instructed to submit no-pay claims once the start of episode claim has been processed, "using their typical coding and billing schedules and processes for Medicare services." We interpret "billing schedules and processes" to mean the no-pay claims should be billed with "full" charges from the hospital's chargemaster. If that is correct, what CMS is in essence asking hospital RO model participants to do is bill the charges for the technical component twice (once to receive payment, and once with the no-pay claim). As a result, hospitals could report the charges twice on their cost report, while only reporting the costs once. This could distort the Medicare cost-to-charge ratio (CCRs) for radiation oncology services at RO model participating hospitals if the agency doesn't clarify how these charges are to be billed and reported.

As the Agency is aware, the CCRs for participating hospitals along with the CCRs for non-participating hospitals will be used as part of the APC weight setting process in future years. Given CMS has designed the model to include 30% of all RO services nationally, the number of hospitals included in the model and the volume of services would distort the data used to set APC weights, if charges submitted on claims for payment and no-pay claims are not appropriately accounted for by participating hospitals and the agency during the billing, cost reporting, and APC weight setting processes. **This will result in under-reimbursing radiation oncology services in future years, but also increasing Medicare payments for all other services paid using the APC schedule given the weighting system's inherent budget neutrality. Therefore, we ask CMS to clarify its billing and cost reporting instructions and take appropriate steps to ensure that a distortion of APC weights does not occur as a result of the RO model.**

Extreme and Uncontrollable Circumstances

In the 2022 HOPPS Proposed Rule, CMS is proposing to adopt an Extreme and Uncontrollable Circumstances (EUC) policy for the RO Model. The Agency is proposing to define an EUC as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to delivery care in accordance with the RO Model's requirements and affects the entire region or locale. CMS proposes that if it declares an EUC for a geographic region, then it 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. In a national, regional, or local event, CMS proposes to apply the EUC policy only if the magnitude of the event calls for the use of special authority to help providers respond to the emergency and continue providing care.

Furthermore, CMS proposes the following factors for helping identify RO Model participants that are experiencing EUCs:

[5] RO Model Billing Webinar, https://innovation.cms.gov/media/document/ro-model-coding-billing-pricing-webinar-aug24

- Whether the RO participants are furnishing services within a geographic area considered to be within an "emergency area" during an "emergency period" as defined in section 1135(g) of the Social Security Act.
- Whether a state of emergency has been declared in the relevant geographic area.

ASTRO thanks CMS for establishing an EUC policy for the RO Model. After last year's final rule was issued, we heard from RO Model participants who experienced devastating hurricanes and forest fires that destroyed entire communities. They continued to provide care during not only the COVID-19 PHE but also as these events were destroying the fabric of their communities. How unfortunate that at the time, many were also concerned about having to participate in the RO Model, an added and quite frankly unnecessary concern given the circumstances. We appreciate CMS rectifying this issue.

The proposed rule indicates that an EUC would apply to a "geographic region or geographic area." **ASTRO urges CMS to provide additional clarity regarding how it will determine "geographic region or geographic area" as it applies to the EUC Policy. Furthermore, we urge CMS to opine on whether it would consider expansion of the COVID-19 public health emergency as meeting the criteria for a delay in the implementation date of the RO Model. Given the continued rise in Delta Variant cases, forcing clinics to delay cancer surgeries and other drastic measures, we are hearing from radiation oncology practices that COVID has never been worse in their communities, and they are deeply concerned about implementing the RO Model in the midst of one of our nation's ongoing dire public health emergency.**

Health Equity Achievement in Radiation Therapy (HEART)

ASTRO has recommended numerous reforms to the RO Model to ensure it achieves the goals of higher quality, while still reducing costs for Medicare and patients. As mentioned in our June 18, 2021 letter to the Agency, these reforms and others should also be made to address healthcare disparities. The RO Model represents a distinct opportunity to address healthcare disparities that should not be overlooked.

ASTRO urges CMS to establish a Health Equity Achievement in Radiation Therapy (HEART) payment for wraparound services to address healthcare disparities. This concept is very similar to the Monthly Enhanced Oncology Services (MEOS) payment that is applied in the Oncology Care Model. HEART payments could support services, not currently billable, such as:

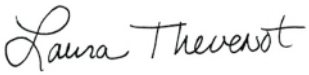
- Triage patient needs 24/7;
- Provide patient care navigation, including patient education and symptom management, as well as financial support;
- Assess and address patient's nutrition, transportation and lodging needs, personal support system and identify resources to address barriers to accessing treatment and compliance with treatment care plan;
- Coordination of care and communication of information following evaluation and treatment with other care providers engaged in the patient's treatment;

- Established care plan that contains 13 components of the Institute of Medicine Care Management Plan that is documented and reviewed during each patient visit; and
- Documented survivorship plan that are developed in coordination with the patient, as well as other care providers and issued upon completion of treatment.

Data associated with those episodes with a HEART payment could be collected and used to determine the effectiveness of HEART interventions. By learning more about what causes these disparities and understanding what interventions are most effective and are closing gaps, the model could test measures to ensure participants are accountable for reducing disparities. Over time, measures could potentially involve treatment refusals, interruptions and completion of the RT episode of care, and duration of treatments.

As previously stated, ASTRO is committed to the establishment of an alternative payment model for radiation oncology. We continue to believe that, if crafted appropriately, the model can be a significant step toward value-based payment and health equity. While we are disappointed that CMS has not addressed our concerns, nor those of the radiation oncology community, health policy experts, and Congress, we remain steadfast in our commitment to raise these issues and push for RO Model modifications on behalf of our members and the patients they serve. If you have any questions, please contact Anne Hubbard, ASTRO Director of Health Policy at 703-839-7394.

Sincerely,



Laura I. Thevenot
Chief Executive Officer

Joseph Biden, President of the United States
Xavier Becerra, Secretary, Department of Health and Human Services
Elizabeth Fowler, Deputy Administrator and Director, CMS Center for Medicare and Medicaid Innovation (CMMI)
Amy Bassano, Deputy Director, CMMI
Christina Ritter, Director, CMMI Patient Care Models
Lara Strawbridge, Director, CMMI Division of Ambulatory Models
Marcie O'Reilly, Health Insurance Specialist, CMMI

Enclosures:
All Previous Comment Letters