

ASTRO Response to 2022 RO Model Proposed Rule

Executive Summary

An overemphasis on demonstrating savings under the RO Model has sacrificed achievable goals of quality improvement and payment stability. Despite the indefinite delay of the RO Model, ASTRO remains committed to working with CMS and Congress to establish a radiation oncology payment reform initiative that contributes to President Biden's strategy to reduce cancer mortality.

ASTRO's comment letter on the RO Model Proposed Rule outlines pathways to achieve the following outcomes:

Rate Stability and Burden Reduction

- Reduce payment cuts that jeopardize the ability of people with cancer to receive state-of-the-art care close to home.
- Simplify payment methodologies to ensure fair and stable reimbursement that recognizes the efficient delivery of care.
- Invest in the cancer treatment infrastructure necessary to ensure patient access to high quality care using advanced technology.
- Eliminate unnecessary and burdensome reporting requirements that do not contribute to improved patient outcomes.
- Reduce reliance on prior authorization as a blunt tool for reducing the cost of care.

Health Equity

- Establish mechanisms to identify and support patient populations with limited access to radiation therapy, to ensure initiation and completion of treatment.
- Reduce healthcare disparities by capitalizing on evidence-based approaches to advance health equity.
- Invest in wraparound services, including patient navigation and transportation, that improve care for people from historically marginalized populations.

Continuum of Care

- Provide a path for total cost of care (TCOC) models to recognize the value and quality of radiation therapy within a broader continuum of cancer care.
- Require multidisciplinary collaboration as part of the initiating service within a TCOC model.
- Establish discrete episodes within broader TCOC models to recognize the value of services, like radiation therapy, in multimodality treatment.



TARGETING CANCER CARE

June 1, 2022

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RE: Radiation Oncology Model CM-5527-P2

Dear Administrator Brooks-LaSure:

On behalf of the members of the American Society for Radiation Oncology¹ we are responding to 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, as well as the pending announcement associated with the Oncology Care Model (OCM).

ASTRO believes the RO Model process has stalled due to the Agency's overemphasis on model savings over quality improvement. In this comment letter ASTRO seeks to:

- Simplify the overly complex and burdensome mandatory participation requirements, payment methodology and reporting requirements that combine to put at risk the ability of practices to provide state-of-the-art cancer care close to home.
- Reduce healthcare disparities that could be exacerbated under the RO Model, and instead capitalize on evidence-based approaches to advance health equity.
- Provide a path for total cost of care models to recognize the value and quality of radiation therapy within a broader continuum of cancer care.

¹ASTRO 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 patients with cancer 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.

In the proposed rule, CMS notes that it continues to believe that the “*RO Model would address long-standing concerns related to RT delivery and payment, including lack of site neutrality for payments, incentives that encourage volume of services over the value of services, and coding and payment challenges.*” Sadly, after more than 5 years of work by the Agency and stakeholders, the RO Model failed to address these issues and live up to its great promise. We believe that an overemphasis on demonstrating savings under the model has sacrificed achievable goals of quality improvement and payment stability. Nonetheless, ASTRO believes these worthy goals remain within reach, and we are committed to working with the Agency and Congress to make the necessary reforms to the RO Model, or to undertake a new payment reform initiative that would contribute to President Biden’s strategy for fighting cancer.

In addition to securing rate stability and the promotion of high-quality care for Medicare beneficiaries, the Agency also acknowledges that stakeholders, ASTRO included, value the RO Model and are dedicated to preparing for its implementation. These sentiments echo the November 2017 Report to Congress, in which 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 therapy services could be tested to determine if they reduce expenditures while maintaining or enhancing quality of care.”²

The Agency’s statements are also reflective of the support the concept of the RO Model has secured from Members of Congress. An October 2021 letter signed by 18 bipartisan US Senators stated:

“we believe implementation of the RO Model could benefit both health care providers and Medicare enrollees alike. Prospective episode-based payments, if structured correctly, can provide stable and sustainable payments for these life-saving services while helping ensure seniors are able to access care in their own communities...”

A similar letter was signed by 66 bipartisan Members of the House of Representatives.

Each of these letters also addressed the shortcomings of the RO Model and weighed in on changes to improve it:

“...we again urge CMS to address remaining concerns with the breadth and mandatory nature of the model. Specifically, we encourage the agency to consider additional reforms, such as further adjustments to the discount factors and reductions to

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

administrative burdens that would assist in facilitating our shared goal of advancing value-based cancer care.”

A third letter, submitted by the House of Representatives Quad Caucus, representing the Congressional Asian Pacific American Caucus, the Congressional Black Caucus, the Congressional Hispanic Caucus, and the Congressional Native American Caucus, stated the following:

“RO Model represents a new opportunity to address health disparities in radiation therapy. Unfortunately, the proposed combined cuts undermine the promise of the RO Model and the chance to improve health equity. To target health disparities, a Health Equity Achievement in Radiation Therapy (HEART) payment should be designated for wraparound services, such as transportation and other social supports, as a core component of the RO model. Poor social determinants of health lead to worse outcomes in many neighborhoods across our country, and a substantial body of evidence suggests that these must be considered and incorporated for value-based payment models to be successful.”

In addition to Congressional interest and support of the RO Model, there have been numerous stakeholder groups that have also expressed support for a modified payment model. In an April 6, 2021 letter, the Health Care Transformation Task Force stated:

“Many stakeholders have come to view the RO Model as primarily a rate reduction effort rather than a sincere attempt to reform care delivery in a manner that promotes the use of appropriate clinical pathways with a focus on improving quality... We encourage CMS to: 1) reevaluate the downside-only design of the discount and withhold process and consider incorporating upside incentives for improving quality and efficiency, 2) incorporate a glide path structure that allows providers with less APM experience to accept increased risk over time, and 3) evaluate the potential adverse impacts of historically efficient providers and providers serving under resourced communities to ensure that access to care is not adversely impacted under the model.”

Furthermore, the broader cancer community has also urged support for the RO Model with modifications. A March letter from the Cancer Leadership Council stated the following:

“We are concerned that efforts to generate substantial savings in the RO Model, particularly through excessive discount factor cuts, could affect patient access to care, including access to state-of-art care in certain locations. We understand the difficult balance of designing a sustainable system that protects access and encourages innovation, but it is a balance that must be pursued.”

After five years, despite all of this support, not only from the Agency, but also from Members of Congress and the broader oncology community, we have little to show for it due to CMS’ unwillingness to fine tune the model to ensure that practices can successfully participate. We are so close, yet so far away from implementing a payment model that could meaningfully shift

radiation therapy from fee-for-service to value-based payment while at the same time providing Medicare beneficiaries with access to high-quality care. This is not only disappointing to those that have put significant time and effort into this project, but it is also a disservice to the many Medicare beneficiaries who would have benefited from a refined payment model.

CMS' actions in response to reasonable concerns raised regarding the impact of the RO Model are in misalignment with historical statements that are supportive of the RO Model. Additionally, they are also contrary to 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.

As a reminder, ASTRO entered into thoughtful and collaborative discussions with the Centers for Medicaid and Medicare Innovation Center (CMMI) starting in 2015 on the development of an alternative payment model for the field of radiation oncology because we believe 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.

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.

RO Model Flaws and Fixes

Mandatory Participation

CMS identified practices in select Core Based Statistical Areas (CBSAs) for mandatory participation in the RO Model. ASTRO has long-supported voluntary participation in a radiation oncology APM, and we remain very concerned about a model that requires mandatory participation at the outset. 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. Additionally, it has the potential to create competitive disadvantages for those

participating in the model, and impose financial hardships on practices that have significant fixed costs unmatched in medicine. CMS' approach would ultimately fracture radiation oncology, a high value, relatively low-cost oncology service.

Additionally, mandatory participation is not supported by Section 1115A of the Social Security Act, which authorizes CMMI to "test" a new payment and service delivery model. ASTRO continues to believe that the mandatory nature of the RO Model exceeds the rational limits of CMS' authority in that it mandates participation by radiation therapy providers in randomly selected zip codes,³ with only limited exclusions⁴. This expansive mandatory model goes far beyond any demonstration program that CMS has put into place thus far, and could seriously jeopardize access to radiation care in the most vulnerable populations. The level of participation is beyond the scope of what is needed to test CMS' objectives and appears to be driven solely by the desire to meet a predetermined savings estimate, and seems to be reactionary to disappointing prior model outcomes.⁵

CMS is authorized to conduct tests "while preserving or enhancing the quality of care." In other words, any model or test that decreases quality of care will exceed CMS' statutory authority. The RO Model will decrease quality of care due to the punitive nature of the Model's payment methodology and burdensome reporting requirements. Voluntary models allow providers to opt in when they believe that the terms of the demonstration allow them to deliver high quality care and decline to join when the demonstration may lead to a lower quality care; the proposed mandatory model eliminates this safeguard. Forcing unready practices to participate, while simultaneously prohibiting others that are well-prepared, is problematic.

Should CMS decide to move forward with the RO Model, ASTRO urges CMS to initiate it on a voluntary basis with little to no risk. A transition to a risk-based model with opt-in and opt-out provisions can then take place over a period of time. This approach is similar to how the Agency instituted the Comprehensive Joint Replacement model, which allowed for a one-year transition without any downside risk, as well as the Oncology Care Model that features a multi-year one-sided risk component that transitions to two-side risk either voluntarily or due to a practice's inability to earn a performance-based payment. These types of opportunities provide participants with pathways to value-based payment recognizing the need for flexibility and time to adjust practice patterns and adjust to the model's requirements.

Savings

ASTRO remains greatly concerned that the RO Model merely tests a payment cut. The Agency's focus on reducing Medicare expenditures disregards the opportunities that exist to improve quality of care through realigned incentives that encourage the use of guideline concordant care that leads to less variation in treatment, greater efficiency, patient convenience, and improved clinical outcomes.

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*

³ 84 Fed. Reg. 34478, 34568.

⁴ 84 Fed. Reg. 34478, 34494.

⁵ 84 Fed. Reg. 34478, 34568.

lasting transformation and a broader array of quality investments, rather than focusing solely on each individual model's cost and quality improvements."⁶ We agree, but the RO Model, as it is currently crafted, is wholly inconsistent with this vision. 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 corrupted this promising approach.

Payment Methodology

The RO Model payment methodology, with its eight distinct steps, is far too complex and cumbersome. Initially, even CMS officials struggled to explain it and wound up using ASTRO's payment methodology workbook as part of educational its efforts to inform practices that were identified for participation. While imitation is the sincerest form of flattery, it's striking that Agency officials responsible for informing and educating the broader radiation oncology community also found modeling the payment methodology too complex and difficult to explain. This is particularly frustrating given CMS' efforts to simplify and streamline other programs.

Site Neutral Test and National Base Rates

The RO Model is a "site neutral test" that establishes a common National Base Rate for services regardless of where they are furnished. When this concept was proposed, the Agency believed that it would offer RO participants more certainty regarding the pricing of radiation therapy services and remove incentives to promote the provision of radiation therapy services at one site over another.

To establish this site neutral test, 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. Over the years, the Agency has stood firm on its decision to use HOPD episodes, rather than freestanding and HOPD episodes, because it believes Outpatient Prospective Payment System (OPPS) payments have been more stable over time and have a stronger empirical foundation, because they are derived from hospital cost reports, rather than those under the Medicare Physician Fee Schedule (MPFS).

ASTRO has supported the proposal of a site neutral test and appreciates the Agency's commitment to providing participants with stable rates. However, we remain concerned about CMS' decision to establish the site neutral test based on OPPS data alone. The value of professional services is derived the same way for both the hospital and freestanding setting. Additionally, despite CMS' assertion regarding the lack of rate stability in the MPFS, the rates for treatment planning, treatment management and other professional service codes have remained stable over the past several years, due to the passage of the Patient Protection and Medicare Protection Act which froze rates beginning in 2016. Therefore, ASTRO

⁶ 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/doi/10.1377/hblog20210812.211558/full/>

continues to believe that a blend of the historical PFS and OPFS rates for the PC of each cancer type will establish more accurate payment rates.

Furthermore, we remain concerned that the data points used to formulate the National Base Rates inappropriately included palliative care cases that distort the true cost of care. The data associated with palliative care cases should be aggregated to establish a separate “Cancer Symptom Palliation, Not Otherwise Specified” episode to account for these cases.

Finally, while we agree with the use of HOPPS rates for the TC payment for each cancer type as part of the site-neutral test, we believe it is important to again express our concern about the OPFS Comprehensive-Ambulatory Payment Classification (C-APC) methodology. The methodology seeks to package payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPFS at the claim level. ASTRO has for several years expressed great concern that the one-size-fits-all C-APC methodology is poorly suited and wholly inappropriate for radiation oncology services. Radiation oncology essentially requires component coding to account for several steps in the process of care (consultation; preparing for treatment; medical radiation physics, dosimetry, treatment devices and special services; radiation treatment delivery; radiation treatment management; and follow-up care management). CMS’ C-APC methodology does not account for this complexity and fails to capture appropriately coded claims, resulting in distorted data leading to inaccurate payment rates that jeopardize radiation therapy services due to artificially low reimbursement rates.

Trend Factor Modification

ASTRO has also previously pointed out that trend factor instability is not limited to the volume component of the methodology. Because the trend factor is also reliant on yearly Medicare Physician Fee Schedule (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 particularly important for radiation oncology, given the significant MPFS cuts that the specialty has experienced in recent years and the future vulnerabilities that exist in that payment system. 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.

In the 2022 OPFS final rule, CMS modified the volume component of the RO Model trend factor to address significant utilization shifts for the PC and/or TC of an included cancer type. This addressed situations in which 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 performance year (PY) to increase or decrease by more than 10 percent compared to the corresponding trend factor of the previous calendar year (CY) when Fee-for-Service (FFS) payments are held constant with the previous CY.

Rather than establish a threshold triggering the modification, ASTRO urged the Agency to 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 COVID-19 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 will 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 preserves 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.

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. CMS anticipated that based on these discounts it would be able to save \$150 million in Medicare FFS spending over the five-year demonstration period.

CMS' argument that reducing the discount factors would necessitate increasing the number of RO Model participants further demonstrates the overemphasis on model savings above quality improvement, not to mention the financial viability of RO Model practices that are mandated to participate. 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 radiation oncology clinic. Practices will struggle to invest in the human and technological infrastructure to provide high quality, state-of-the-art care. CMS estimated, in the 2022 OPSS final rule, that on average, Medicare FFS payments to Hospital Outpatient Departments (HOPDs) would decrease by 9.9 percent over the duration of the model demonstration period.

ASTRO performed its own analysis, which demonstrates that the RO Model creates far more "losers" than "winners," with discount factors set at this level. While we can appreciate that a shift toward episode-based payment through a value-based construct will result in winners and losers, the spread should be more equal on both sides of the equation. Unfortunately, CMS isn't looking to level the playing field for radiation oncology payment, but rather seems to be taking a nuclear approach to generate saving off what is already a very high value form of cancer treatment, particularly when compared to other modalities of cancer treatment.

APM v FFS		
Impact (PY1-5)	PC Providers	TC Providers
< - 20%	0.0%	0.0%
-20% to < -10%	0.8%	22.7%
-10% to < -5%	12.1%	45.4%
-5% to < -1%	39.7%	1.4%
-1% to < +1%	25.9%	0.8%
+1% to < +5%	19.0%	10.9%
+5% to < +10%	1.9%	16.5%
+10% to < +20%	0.3%	2.2%
=> +20%	0.2%	0.1%

ASTRO continues to recommend that the Agency set the discounts at 3% or less. Reducing these cuts to 3% will still generate significant savings for Medicare and better align the RO Model’s discount factors with those of other APMs. Additionally, discount factors at this level will allow practices to continue investing in the equipment necessary to deliver high quality cancer care.

Case Mix Adjustment, Historical Experience Adjustment and Blend

The RO Model payment methodology includes the use of practice specific case mix and historical payment data as part of the eight-step payment methodology. While we appreciate the use of historical data to establish a payment rate that is comparative to existing rates that practices receive, the process by which the Agency pursued sharing the Case Mix Adjustment and Historical Experience Adjustment over the last several years was not transparent and raised numerous questions.

Radiation oncology practices that are compelled to participate in the RO Model had no way of knowing whether CMS accurately calculated their Case Mix Adjustment and Historical Experience Adjustment. Additionally, they do not receive this data until 30-days prior to the beginning of the performance period, so there is no way to dispute incorrect data let alone plan for the coming year. If CMS is going to force participation, the Agency needs to be more open and collaborative with radiation oncology practices that are compelled to participate. Sufficient time should be provided to allow practices to prepare, and there should also be opportunities for an open dialogue with the Agency so that practices can feel confident that they are being fairly reimbursed for services.

Additionally, the Case Mix Adjustment is designed to account for care patterns and factors that are beyond the RO participant’s control and tend to vary by practice, such as cancer type; age; sex; presence of major procedure; death during the first 30 days, second 30 days, or last 30 days of the episode; and presence of chemotherapy. The Case Mix Adjustment is applied to the PC and TC component for each disease site. To do this, the Agency measures the occurrence of the case mix variables among the beneficiary population that each RO participant has treated historically compared to occurrences of these variables in the national beneficiary profile that occurred in the HOPD setting.

Case Mix does not recognize the impact that COVID-19 has had and will continue to have on cancer patients. Many are seeking treatment after a delayed diagnosis; therefore, their disease is more complex and likely requires more expensive treatment. A practice's case-mix experience prior to 2020 and its current case-mix are likely to be very different. However, the Agency has disregarded ASTRO's concerns regarding the impact of COVID-19. This is particularly disappointing given the significant evidence demonstrating that cancer rates are increasing and more complex because of delays in diagnosis and treatment due to the COVID-19 PHE.^{7,8}

Finally, CMS applies a "Blend" to the payment methodology to recognize practices that are already providing high quality, efficient care, while also bringing less efficient practices into alignment with National Base Rates for the term of the model. ASTRO raised issues with what was originally termed the "Efficiency Factor" in response to the July 2019 RO Model proposed rule. When ASTRO met with CMS officials, shortly after the initial proposed rule was issued, it was clear that they were somewhat confused by the "Efficiency Factor" and unable to fully explain its role in the payment methodology. Rather than address the issues at hand, the Agency simply changed the term "Efficiency Factor" to "Blend" without addressing the underlying issues, which are threefold:

- 1) The Blend harms practices that are already efficient. They are financially penalized when the cost of a patient's care (an outlier episode) exceeds the episode-based payment rate because their historic rates are so low.
- 2) The Blend overpays inefficient practices in comparison to efficient practices, again putting those efficient practices at a disadvantage.
- 3) The Blend does not recognize the appropriate use of more expensive modalities of treatment and automatically designates those practices that primarily use these modalities as inefficient.

The Blend is nothing more than a poorly thought-out payment cut. It accomplishes nothing, yet year after year, CMS keeps trotting it out. As such, we are again trotting out our simple analysis demonstrating how ridiculous this concept really is.

⁷ Grady, Denise. "The Pandemic's Hidden Victims: Sick or Dying, but not from the Virus." New York Times. April 20, 2020.

⁸ McGinley, Laurie. "COVID and Cancer: A dangerous combination, especially for people of color." Washington Post. October 11, 2021.

EFFICIENCY FACTOR ANALYSIS-BLEND ANALYSIS				
	Efficient Practice		Inefficient Practice	
Subtotal	\$	3,389.40	\$	3,389.40
Case Mix Adjustment		0.04		0.04
Historical Experience Adjuster		-0.1		0.13
PY1 Efficiency Factor		0.9		0.9
Combined Adjustments		0.95		1.16
Subtotal	\$	3,219.93	\$	3,921.54
			\$	701.61
				21.8%

A recent Journal of the American Medical Association underscored concerns about benchmarking based on historical costs⁹. The article pointed out that efficient practices are disadvantaged because ultimately, they will face progressively lower benchmarks, which will be far more challenging to meet because they are already efficient. The article recommended an “efficiency floor,” which could be adjusted over time or designed to reflect things like historical spending or case-mix. ASTRO urges CMS to consider a similar construct that would protect efficient practices but also establish an adjustment to reflect appropriate use of more expensive modalities of treatment, i.e. more high value based therapies that improve target coverage or normal tissue avoidance widening the therapeutic window and hypofractionation regimens, so that efficient practices are not disadvantaged under an alternative payment model.

Waiver of 5% bonus on Technical Services

In the 2020 RO Model final rule, CMS 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. There is no more damning piece of evidence demonstrating that the RO Model is designed as a payment cut than CMS decision to simply cast aside Medicare law’s requirement to apply a 5% bonus for technical payments. 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 it 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.

⁹ Joynt Maddox KE, Shashikumar SA, Ryan AM. Medicare’s Bundled Payment Models—Progress and Pitfalls. *JAMA*. 2022;327(18):1761–1762. doi:10.1001/jama.2022.6402

Quality Measures and Clinical Data Elements

Quality Measures

CMS adopted the following set of quality measures for the RO Model to assess the quality of care provided during episodes. The Agency believes these measures allow it to quantify the impact of the Model on quality of care, radiation therapy services and processes, outcomes, patient satisfaction, and organizational structures and systems.

Quality Measure	Level of Reporting	Pay for Reporting	Pay for Performance
Oncology: Medical and Radiation – Plan of Care for Pain (NQF41 #0383; CMS Quality ID #144)	Aggregate	N/A	PYs 1-5
Preventative Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality Data ID #134)	Aggregate	N/A	PYs 1-5
Advanced Care Plan (NQF #0326; CMS Quality ID #047)	Aggregate	N/A	PYs 1-5
Treatment Summary Communication – Radiation Oncology	Aggregate	PYs 1-2	PYs 3-5

Plan of Care for Pain

ASTRO remains concerned about the inclusion of the Oncology: Medical and Radiation – Plan of care for pain (NQF41 #0383; CMS Quality ID #144) quality measure, particularly given that CMS has decided to remove this measure from the IPPS, HOPPS and MIPS quality reporting programs. It is difficult to understand why this measure continues to be included in the RO Model, when the Agency decided that it has no value in the other programs.

CMS recognizes that #144 was developed as a paired measure with Oncology: Medical and Radiation – Pain Intensity Quantified (NQF #0384; CMS Quality ID #143). The pairing is to determine which patients have pain of any level and then document a plan of care for those patients. The Agency also acknowledges that without the quantification measure, RO Model participants will not be able to ensure a correct denominator population to CMS. While the Agency does not require reporting on #143, it will still need to be quantified and RO Model participants will not receive any acknowledgement through the Aggregate Quality Score (AQS) for collecting this data. The Agency should account for the work involved to collect this data through the AQS.

Preventative Care and Screening: Screening for Depression and Follow Up Plan

ASTRO agrees that the Preventative Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality Data ID #134) quality measure is important; however, it is not generally part

of radiation oncology clinical care. Given growing concerns regarding behavioral health and the need to identify patients who require interventions, ASTRO believes this measure should be designated as pay for reporting. This will further incentivize compliance with this measure but also ensure that practices can provide patients presenting with depression with the resources and supports necessary to ensure they are able to initiate and complete treatment.

Clinical Data Elements (CDE)

ASTRO has made every possible [effort](#) to engage with the Agency on the development of appropriate data element collection methods, yet key elements are missing that we continue to champion in this comment letter. There needs to be alignment with the existing MIPS reporting parameters, so that those practices accustomed to reporting through MIPS can seamlessly transition to the RO Model. CMS must also provide participating practices with the financial resources to satisfy these requirements as outlined in the Submission Guidance document.

ASTRO understands why CMS wants to collect this data and we appreciate the need to use this information to inform future quality measures, which we agree are at a paucity for the specialty. However, the process of doing this through the CDE collection requirements as laid out by the Agency would be daunting for many practices. CMS must consider the following modifications:

- Drop the delivered dose requirement and use prescribed dose
- Provide clarification regarding staging requirements
- Delay the CDE requirements for two-years

According to the Quality Measures and CDE guidance document, CMS is assigning unique numeric identifiers for the collection of anatomic site, lymph nodes, fractions, dose per fraction, total dose, laterality, histology, intent, ISUP grade, Gleason and more. Anatomic target and laterality are included in ICD-10 codes. Reporting this data using distinct codes is duplicative and unnecessary. Additionally, it increases overhead costs due to the need to hire additional staff and is in direct contrast to ONC and CMS regulations that promote movement to FHIR-based exchanges.

COC-centric Regulations. CMS is requiring RO participants to collect target, dosage, and fractionation data in the same manner as required by facilities accredited by the Commission on Cancer (COC). None of the data currently collected by COC has resulted in any quality measures specific to radiation oncology for any of the included disease sites, it is doubtful that this exercise would yield anything different. The COC is a voluntary group of 1,500 hospitals who perform the vast majority of cancer surgeries. This places an additional burden on those radiation oncology practices that are not COC accredited, particularly freestanding and rural practices that would have to hire trained cancer registrars. Furthermore, the COC standards related to radiation therapy are minimal, due to the fact that COC is sponsored by the American College of Surgeons, and thus their standards are focused on surgical

procedures. Lastly, we will note that several publications^{10,11} have discussed the limitations of radiation therapy data in National Cancer Database (NCDB), underscoring that the COC framework may not be reliable in the realm of radiation oncology.

Dose per fraction (3.2.1.3). CMS requires the actual number of fractions delivered rather than the number of fractions prescribed. Treatment delivery information is cumbersome to extract from treatment planning systems and can report out differently depending on how the treatment was planned, making it useless for the purpose of data analytics. Unlike medical oncology where the treatment plan may vary from the initial prescription with changes based on patient tolerance to treatment, in radiation oncology the difference between the planned dose and the delivered dose is not significant and rarely has any clinical consequence. ASTRO thinks the minimal difference between the prescribed dose and the delivered dose does not warrant the time and burden associated with reporting on the delivered dose as it has no clinical impact on patient outcomes.

Cancer Stage (3.3.1). CMS requires the AJCC, T, N and M values that are documented closest to the start of the 90-day episode. Cancer patients have complex medical records with many different staging events on different dates and even different types of staging. In the context of clinical data element reporting, ASTRO urges CMS to provide additional clarification regarding whether the staging reported is the staging performed prior to the treatment date on the date closest to the date of radiation treatment or staging occurring after the treatment date. Based on the timing, this may require additional diagnostic testing, which would result in increased costs and patient burden. Additionally, CMS should clarify whether the staging reported is clinical staging or pathological staging. If both clinical and pathological staging occur on the same date, and are both required for reporting, should there be a preference for reporting pathological staging over clinical staging?

CMS is requiring that all CDEs will need to be manually reported utilizing a template provided by CMS. This will take significant time and resources. Freestanding RO Model participants, who unlike voluntary COC hospitals do not have registrars in place to collect this data, will be forced to hire and train staff to interpret and record the various elements in the patient record, and then manually input them correctly into the template. Otherwise, physicians and clinical staff will be required to input this data detracting from patient care. This is coming at a time when practices are still reeling from the financial impact of COVID-19 and many are currently experiencing staffing shortages. According to one RO Model participant, it would take upwards of 20 minutes to input each of the data points for each breast cancer case. Coupled with the CDE reporting requirements for the other disease sites, this presents a significant burden for practices. CMS must allow for greater flexibility in the data submission requirements, recognizing that some practices may not be able to readily extract this data from existing systems and submit it to the Agency.

ASTRO has urged CMS multiple times to find areas of alignment between existing MIPS reporting requirement processes and those associated with the RO Model to reduce reporting burden. We have

¹⁰ Jairam, V., & Park, H. (2019). Strengths and limitations of large databases in lung cancer radiation oncology research. *Translational Lung Cancer Research*, 0, S172-S183. Retrieved from <https://tlcr.amegroups.com/article/view/29070>

¹¹ Yang DX, Khera R, Miccio JA, et al. Prevalence of Missing Data in the National Cancer Database and Association With Overall Survival. *JAMA Netw Open*. 2021;4(3):e211793. doi:10.1001/jamanetworkopen.2021.1793

also encouraged the Agency to collaborate with radiation oncology EHR vendors to identify those elements that can easily be extracted from existing systems before expanding data collection requirements. We are disappointed that these recommendations continue to fall on deaf ears and the Agency would rather pursue a manual input system than engage with stakeholders on establishing a more meaningful process for data collection.

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. This time would not only allow for new standards to be implemented, but also vendor compliance with USCDI, TEFCA, and 21 Century Cures Act mandates. The considerable amount of growth in healthcare data standardization expected during the next two years could provide a streamlined method for practices to collect and report this data. 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. RO Model participants could still be compliant with quality reporting through the quality measures, if the CDE aspect is delayed.

Finally, CMS has established three distinct reporting periods associated with CDE and Quality Measures data reporting. CDEs are reported biannually by July 31 for episodes ending between January 1 and June 30 and by January 31 for episodes ending between July 1 and December 31. Quality measures data must be submitted by March 31 after the end of each performance period. The Agency must combine all three reporting periods into one: March 31.

Additionally, successful reporting of CDE's is set at 95% of RO beneficiary episodes completed during the performance year. This threshold is incredibly high, and it will be an extreme burden for practices to report data multiple times per year. 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

CMS has previously stated that “any failure, however minor,” to comply with the following RO Model monitoring requirements will jeopardize a practice's ability to be recognized as an Advanced APM participant:

- 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;

¹² The Minimal Common Oncology Data Elements (mCODE™) initiative provides both a common data language and an open-source, nonproprietary data model for interconnectivity across systems.

¹³ CodeX (Common Oncology Data Elements eXtensions) is a Member-driven HL7 FHIR Accelerator, building a community to accelerate interoperable data modeling and applications that lead to step-change improvements in cancer patient care and research.

- 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.

Despite CMS' choice of language that is derogatory in tone, ASTRO has never disagreed with the value of the activities associated with the monitoring requirements. We have merely 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. Thus, it is very disappointing that the Agency should use such punitive language associated with this requirement.

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—again only the excessive payment cuts as described in the payment methodology. 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 CMS has never provided 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.

An alternative and more simplified approach to these monitoring requirements would be to establish an accreditation requirement as part of the RO Model. Accreditation standards include each of these components as part of the assessment. ASTRO's Accreditation Program for Excellence® (APEX) Standards identify systematic quality and safety approaches that build on and reinforce regulatory requirements to add value for practitioners and health care consumers. The APEX standards translate the goals outlined in the *Safety is No Accident* framework into objective, verifiable expectations for performance in radiation oncology practice and align to the itemized monitoring requirements¹⁴.

Cost of Compliance

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

One mid-western hospital system 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 and workflows.

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.

Achieving Health Care Equity in Cancer Care

Up until recently, very little attention has been paid to the impact of payment models on healthcare inequity. A recent Health Affairs article points to the fact that many of the existing policies are "color blind" and do not recognize the unequal social structures that exist. This puts providers that serve populations experiencing higher rates of healthcare inequity at greater risk for penalties associated with payment models¹⁵. Unfortunately, CMS perpetuates the risk associated with caring for disadvantaged

¹⁴ *Safety is No Accident: A Framework for Quality Radiation Oncology Care*. American Society for Radiation Oncology. 2012.

¹⁵ Yearby, Ruqaiijah; Clark, and Figueroa. "Structural Racism in Historical and Modern US Health Policy." Health Affairs. February 2022, 41:22 p. 187-194.

populations through the RO Model, despite ASTRO's efforts to highlight these challenges and advocate for policies to address them.

In the 2022 OPSS final rule, CMS stated it has no evidence or data to suggest the RO Model will exacerbate 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.

ASTRO is extremely disappointed that the Agency ignores expert views on existing health care disparities and the negative impact the RO Model will have on patients who are at risk for experiencing health care disparities, particularly given the recent numerous publications on the topic. One particular publication pointed to the disproportionate impact that the RO Model will have on smaller practices that have fewer opportunities to distribute higher fixed costs and are further disadvantaged due to the fact that they are more likely to treat a higher proportion of Medicare or dual-eligible beneficiaries further limiting revenues to cover costs. The RO Model will further jeopardize their ability to deliver high quality care to vulnerable populations.¹⁶

Finally, our concerns regarding the impact of payment models on healthcare equity were echoed more recently by Dr. Otis Brawley during a May 5th panel discussion on "Patient Experience and Access in Cancer Care, with a focus on Inequities" that was held as part of President Biden's Cancer Cabinet Cancer Moonshot Community Conversation. Dr. Brawley astutely pointed out that healthcare clinics serving disproportionate numbers of Medicare and Medicaid beneficiaries are frequently at a disadvantage when it comes to providing patient navigation services because those payment systems "don't pay their fair share." He suggested that efforts need to be made to ensure resources are available for these providers to address healthcare disparities that are often significantly worse in these communities. The RO Model not only doesn't pay its fair share, it actually strips resources from these practices to achieve its cost-savings goals. Dr. Brawley's comment is another indicator that the RO Model is not in alignment with the President's Moonshot goals nor healthcare transformation in the Medicare payment system.

Impact of RO Model on Healthcare Disparities

A Mayo Clinic analysis of the RO Model indicated that practices caring for socioeconomically disadvantaged populations may face significant revenue reductions, resulting in access to care issues for

¹⁶ Boyce-Fappiano D, Ning MS, Gjyshi O, Mesko S, Pasalic D, Chang AJ, Orio PF 3rd, Thaker NG. Payment Methodology for the Radiation Oncology Alternative Payment Model: Implications for Practices and Suggestions for Improvement. *JCO Oncol Pract*. 2021 Jun 7; OP2100200. doi: 10.1200/OP.21.00200. Epub ahead of print. PMID: 34097458.

the communities they serve.¹⁷ According to the analysis, late-stage disease was historically reimbursed higher than the RO Model base rates. The result is a dramatic reduction in reimbursement for practices that treat patients with advanced disease, which disproportionately impacts minority and rural populations. A recent ASTRO survey indicated that more patients are presenting with advanced disease due to care delays associated with the COVID-19 pandemic.

Decades of research has demonstrated that minority and rural populations frequently present with advanced stage disease due to limited access to preventative services. Black patients (12.3%) and Hispanic patients (10.5%) present with clinically advanced-stage prostate cancer more frequently than White patients (6.3%)¹⁸. Additionally, Black women are more likely than White women to receive a breast cancer diagnosis at an advanced stage of disease¹⁹.

Frequently, patients with advanced stage disease receive palliative radiation therapy, which reduces pain and improves quality of life for patients with metastatic cancer. Despite this benefit, Black patients with prostate cancer are 20% less likely to receive palliative radiation therapy and, for colorectal cancer, 28% less likely to receive palliative radiation therapy when compared to White patients.²⁰ The RO Model could potentially exacerbate these health inequities because the 90-day bundle only recognizes and reimburses for one disease site.²¹ There is no recognition or payment adjustment in the model that accounts for patients with advanced stage cancer that will likely present with a primary diagnosis to one part of the anatomy that also requires treatment of metastatic disease that has spread to another part of the anatomy.

In addition to limited access to preventative care resulting in advanced stage disease, minority populations also struggle with access to care once diagnosed. Preliminary analysis of Medicare data shows that minority patients are nearly one-third more likely than White patients to not even begin their radiation therapy treatments, despite having completed the complex treatment planning process. Additionally, the analysis demonstrates that the factors contributing to an inability to initiate or complete treatment vary by disease site. While it is unclear and we are exploring what prevents some minority patients from beginning radiation therapy treatment, evidence points to lack of transportation, lower socioeconomic status, lack of childcare, inability to take the necessary time off work,

¹⁷ Waddle, MD, MR, Stross, MD, WC, Vallow, MD, LA, et al. "Impact of Patient Stage and Disease Characteristics on the proposed Radiation Oncology Alternative Payment Model (RO-APM)." *Int J Radiation Oncol Biol Phys*, Vol. 106, No. 5, pp. 905-911, 2020. <https://doi.org/10.1016/j.ijrobp.2019.12.012>

¹⁸ Richard M. Hoffman, Frank D. Gilliland, J. William Eley, Linda C. Harlan, Robert A. Stephenson, Janet L. Stanford, Peter C. Albertson, Ann S. Hamilton, W. Curtis Hunt, Arnold L. Potosky, Racial and Ethnic Differences in Advanced-Stage Prostate Cancer: the Prostate Cancer Outcomes Study, *JNCI: Journal of the National Cancer Institute*, Volume 93, Issue 5, 7 March 2001, Pages 388–395, <https://doi.org/10.1093/jnci/93.5.388>

¹⁹ Baquet, Claudia R et al. "Breast cancer epidemiology in blacks and whites: disparities in incidence, mortality, survival rates and histology." *Journal of the National Medical Association* vol. 100,5 (2008): 480-8. doi:10.1016/s0027-9684(15)31294-3

²⁰ Murphy JD, Nelson LM, Chang DT, Mell LK, Le QT. Patterns of care in palliative radiotherapy: a population-based study. *J Oncol Pract*. 2013 Sep;9(5):e220-7. doi: 10.1200/JOP.2012.000835. Epub 2013 Apr 16. PMID: 23943892.

²¹ Parsa Erfani, Jose F. Figueroa, Miranda B. Lam, Reforms to the Radiation Oncology Model: Prioritizing Health Equity, *International Journal of Radiation Oncology*Biophysics*Physics*, Volume 110, Issue 2, 2021, Pages 328-330, ISSN 0360-3016, <https://doi.org/10.1016/j.ijrobp.2021.01.029>. (<https://www.sciencedirect.com/science/article/pii/S0360301621000894>)

underinsured/uninsured, and limited social supports (housing, access to fresh food, etc.) as key barriers. By stripping resources from practices required to participate in the model, instead of capitalizing on the opportunity to address the social determinants of health leading to this gap, the RO model risks worsening health inequities.

Impact on Rural Communities

Cancer incidence and mortality rates in the US are declining, but rural-urban differences in access and outcomes persist. Rural health care providers and their patients face many challenges in the delivery of care, including limited availability of physicians, treatments, transportation barriers, and financial issues among many other difficulties. These challenges often apply acutely to radiation oncology care in rural areas, where studies have long documented health disparities between rural patients and their urban/suburban counterparts. Among the most significant challenges facing rural radiation oncology care is the ability to attract and retain radiation oncology physicians, as well as ensuring access to state of the art and efficient treatments.

While approximately 15 percent of Americans live in rural communities, less than 6 percent of radiation oncologists practice in these communities. A new study found that substantial portion of the U.S. population still suffers from poor geographic access to radiation therapy, with nearly 2% of the US population (6 million people, 1 million of whom are aged 65 or older) live more than 50 miles from a radiation therapy facility. The authors recommend policies and technologies that aid geographically isolated populations to ensure no patient gets left behind, yet again, the RO Model does the opposite²². Rural communities across the country share common healthcare risk factors, including physician shortages, poverty, and remote locations, which contribute to limited access to care. Similar to minority populations, rural populations also present with later stage disease and more complex conditions.²³

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.²⁴ Therefore, rural practices are less likely to have technology that supports shorter, more cost-effective radiation treatment regimens for patients. Additionally, the GAO issued a study on the *Transition to Alternative Payment Models by Providers in Rural, Health Professional Shortage, or Underserved Areas* that further underscores these concerns.²⁵ The report states that providers in rural, shortage, or medically underserved areas face financial, technology, and other challenges in transitioning to APMs due to a lack of capital to finance the upfront costs of transitioning to an APM, including purchasing

²² Maroongroge, MD, MBA, Sean; Wallington, MD, David G.; Taylor, Paige A. et al. "Geographic Access to Radiation Therapy Facilities in the United States." *International Journal of Radiation Oncology-Biology-Physics*. October 22, 2021.

²³ Warshaw, Robin. "Health Disparities Affect Millions in Rural US Communities." *AAMCNews*. October 31, 2017. <https://www.aamc.org/news-insights/health-disparities-affect-millions-rural-us-communities>

²⁴ 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.

²⁵ Government Accountability Office. (2021). *Information on the Transition to Alternative Payment Models by Providers in Rural, Health Professional Shortage, or Underserved Areas*. (GAO Publication No. 22-104618). Washington, D.C.: U.S. Government Printing Office

electronic health record technology; and challenges acquiring data analysis necessary for participation. Cuts, in lieu of investments, are likely to further disadvantage rural clinics and their patients.

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 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.

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. These reforms and others should also be made to address health inequities. For instance, rather than require radiation oncology practices to collect quality measure reporting data that has a limited impact on the quality of care delivered during the episode, CMMI and practices could proactively identify at-risk patient populations and intervene with the provision of wraparound services designed to help them successfully access and complete radiation treatments.

ASTRO continues to recommend the establishment of 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 is developed in coordination with the patient, as well as other care providers and issued upon completion of treatment.

Symptom management clinics or triage units established in oncology settings have proven to be successful at reducing costs and ensuring patients have access to resources that improve their quality of life during their treatment. These units are typically run by nurse care managers that meet with patients during regular clinic visits to assess symptoms associated with radiation therapy and provide guidance regarding self-management, as well as treatment follow up. A 2017 UNC Chapel Hill study demonstrated significant savings associated with the implementation of a symptom management program leading to reduced unnecessary emergency department visits and inpatient admissions²⁶. Programs such as this are currently not reimbursable -- and therefore difficult for smaller practices to establish -- yet have a significant impact on the patient's quality of life and the cost of care.

Additionally, a similar initiative pursued by Cone Health, a regional multi-hospital health system in Greensboro, NC, created a transportation hub to remove barriers to treatment by identifying patients at risk for not pursuing or completing treatment through the establishment of a real-time registry managed by care navigators.²⁷ Treatment completion historically showed statistically significant Black-White differences (Black patients 79.8% vs. White patients 87.3%). The disparity lessened within the intervention period to 88.4% for Black patients and 89.5% for White patients. The program also was found to improve survival over time for Black and White patients and reduce the racial gap in survival among lung and breast cancer patients. A HEART payment could support initiatives such as these to ensure that underserved populations achieve improved health outcomes.

Radiation oncologists typically report that transportation barriers disproportionately impact underserved populations, leading to interrupted and incomplete treatments that negatively impact outcomes. This is particularly challenging given that radiation therapy treatments require daily clinic visits lasting up to 7 weeks. A recent study indicated that regions that have the least access to radiation therapy are disproportionately rural and have older populations that are more likely to be uninsured, which puts these patients at a high risk for not securing adequate care. It is possible that RO Model participants would need waivers from Medicare to provide transportation services to eligible patients, with protections against abuse similar to the safe harbor for local transportation for rural beneficiaries issued by the HHS OIG²⁸.

²⁶ Chera, Bhishamjit S., Reducing Emergency Room Visits and Unplanned Admissions in Patients with Head and Neck Cancer, University of North Carolina Cancer Hospital Lineberger Comprehensive Cancer Center, Clinical Journal of Oncology Nursing – June 2017.

²⁷ Stern, Joseph. Tackling racial disparities in cancer care by creating new ways for institutions to operate." Washington Post, 25 October, 2021

²⁸ <https://www.federalregister.gov/documents/2020/12/02/2020-26072/medicare-and-state-health-care-programs-fraud-and-abuse-revisions-to-safe-harbors-under-the>

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.

Finally, CMS needs to recognize the cost of social interventions that ensure patients have access to care. During a May 5th panel discussion on “Patient Experience and Access in Cancer Care, with a focus on Inequities” that was held as part of President Biden’s Cancer Cabinet Cancer Moonshot Community Conversation, patient advocates asserted that value-based payment should not focus on savings but rather on addressing patient needs and improving quality of life. CMS was urged to recognize the importance of team-based care and the challenges experienced by many patients, particularly those in rural areas who travel long distances to receive treatment. It was pointed out that the CMMI statutory language associated with value-based payment is a barrier because it requires savings, which creates challenges to providing many patients with the navigation services that are really needed yet underfunded or not funded at all. Again, these are misalignments that need to be addressed before value-based payment can move forward in a meaningful way.

The Shift toward TCOC & the Role of Episode Based Payment Models

While ASTRO appreciates CMS’ 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. Episode-based models are appropriate for distinct segments of care that are delivered within a specific period. We believe 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. It involves a unique treatment, delivered over a specific period of time, that involves medical professionals with specific levels of expertise, such as the medical physicist, and expensive capital resources that are not found elsewhere in medicine.

Integrating Care

When a patient is diagnosed with cancer, there should be a referral to a coordinated group of oncology specialists to ensure the patient not only has a variety of treatment options to select, but also, with the assistance of their treatment team, can choose the course of treatment that best aligns with their personal needs and leads to the best possible outcome. For cancer patients in particular, their care is at risk of being compromised when multidisciplinary care involving a combination of medical, surgical and radiation oncology is not considered and ultimately not provided. Care integration can be achieved through TCOC or ACO model constructs. However, the incentives associated with TCOC must be effectively managed to ensure access to effective of multi-disciplinary care, without marginalizing the role of physicians who may operate a freestanding, or an independent practice not associated with an ACO or multispecialty organization. These practices may be disadvantaged if they are required to take

on risk with no reward for treating patients that may be attributed to a larger system as part of a TCOC concept.

One of the best practices for integrating and improving coordination of care between oncology care providers is to require consultation with a broad range of providers representing surgical oncology, medical oncology and radiation oncology, once a cancer care diagnosis has been made. Standards of care exist for the majority of cancer diagnoses today. The National Cancer Institute, ASTRO, the American Society for Clinical Oncology (ASCO), National Comprehensive Cancer Network, and others have issued comprehensive cancer treatment guidelines outlining these standards of care that have been broadly accepted and implemented at cancer treatment centers across the country. These standards enable patients and their care team to consider a variety of treatment options and then choose the course of treatment that best aligns with their personal needs and leads to the best possible outcome. CMS should recognize these existing standards of care and the value they bring to the Biden Cancer Moonshot goals of cutting today's age-adjusted death rate from cancer by at least 50 percent and improving the experience of people and their families living with and surviving cancer through establishing better access to care and social supports, as described above in the section on achieving healthcare equity.

Multispecialty Alignment within TCOC

TCOC models must find ways to better align incentives that take into consideration the providers and costs involved in downstream services. For many existing models, these are usually the greatest generator of savings, yet the initiating provider receives all the risk and reward for participation, whereas there is no risk or reward for the downstream provider. For instance, post-acute care spending accounts for 43% of a Comprehensive Joint Replacement episode, 30% of a BPCI COPD episode, and 23% of a Hospital Readmission Reduction episode²⁹. The savings generated from each of these models is based on reducing the cost of these post-acute services. While the initiating provider, in these cases orthopedic surgeons and the hospital, have plenty of incentive to reduce cost, the providers associated with the post-acute services do not, thus creating misaligned incentives. This misalignment can potentially harm patient care, particularly in the most acute cases in which a downstream provider may believe that a patient warrants additional care and clinical interventions, but the initiating provider is more focused on a spending target.

Drug expenditures account for almost 45% of total episode costs in the Oncology Care Model six-month episode of care³⁰. While CMS uses a novel therapy adjustment to account for new treatment, it does not adequately account for the significant increase in cost associated with these drugs. 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 continue to escalate. When radiation oncology is utilized under a TCOC concept there is also risk that reimbursement for those services will be inadequate, unless CMS ensures that the TCOC payment flows appropriately to all providers

²⁹ Westhead, Monica. "Influence Downstream Provider Behavior: Key strategies to achieve success in an era of risk." Advisory Board. Post Acute Collaborative. 2017.

³⁰ Pittman, Aisha T., Wendy Rossi, and T. May Pini. "Three Benefits to the Oncology Care Model and Four Recommendations to Advance it." Health Affairs. April 22, 2019.

involved. This is particularly concerning for freestanding and independent practices that may not be part of a larger ACO system but are treating patients that are attributed to an ACO.

TCOC models must account for the value associated with each service provided to the patient. CMS has already demonstrated that this is an important consideration through its decision to exclude cardiac rehabilitation (home-based, long-term care) and intensive rehabilitation (hospital-based) from the Bundled Payments Care for Improvement (BPCI)-Advanced Model for cardiology services in the third model year. The Agency recognized that patients who receive care at cardiac rehabilitation facilities have better overall outcomes, yet when these services were included in the BPCI-Advanced model, it was difficult for participants to meet pricing targets, disincentivizing providers from prescribing the service despite its clinical relevance.³¹

Without careful consideration of all of the services delivered to a patient undergoing cancer treatment, CMS runs the risk of setting back all of the advances that have been made in cancer treatment over the last 50 years. A TCOC model must acknowledge and support the sound science associated with existing regimens of multimodality treatment (surgery, chemotherapy and radiation therapy) that have been proven time and again to cure roughly 60% of all cancer patients³². CMS needs to commit to these existing standards of care and support their continued use through reasonable and stable payment rates that include payment for wrap around services that benefit the most vulnerable cancer patients. Cancer treatments that have already demonstrated high-value and quality for the majority of patients treated with cancer should be protected and secured well into the future. As has been previously mentioned, the significant costs of cancer care must be considered based on modality of treatment to ensure that the various providers involved in care can ensure that the patient is getting the best treatment based on their diagnosis and has control over the cost of the therapy that he or she is delivering. Simply putting another care provider “in charge” only risks quality care.

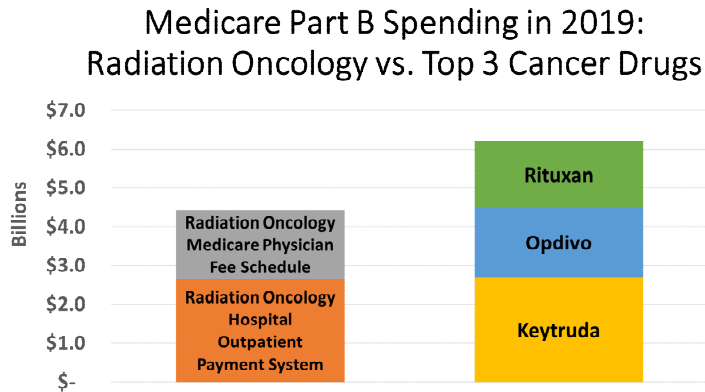
Emphasis on Quality over Cost

Finally, we are 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. As has been previously mentioned, the delivery of radiation therapy relies heavily on significant capital investments, there are limited variable costs from which to generate significant savings. 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.

³¹ “CMS brings much needed changes to rules on TAVRs and Cardiac Rehab in BPCI Advanced.” Archway Health. Accessed May 12, 2022, <https://www.archwayhealth.com/bundled-payments-blog/2019/8/cms-brings-much-needed-changes-to-rules-on-tavrs-and-cardiac-rehab-in-bpci-advanced>

³² “Cancer Treatment & Survivorship Facts and Figures 2019-2021.” American Cancer Society, Inc. <https://www.cancer.org/content/dam/cancer-org/research/cancer-facts-and-statistics/cancer-treatment-and-survivorship-facts-and-figures/cancer-treatment-and-survivorship-facts-and-figures-2019-2021.pdf>

We urge the Agency to keep in mind that Medicare Part B spending for radiation oncology under MPFS and HOPPS was about \$4.4 billion in 2019, which is roughly the same amount Medicare Part B spent on *just two* cancer drugs (Opdivo and Keytruda) during that same period.



When examining the relative cost, cure rates and palliation, radiation oncology is undeniably a high value cancer treatment. The Agency’s excessive focus on radiation oncology savings is misguided, particularly given the skyrocketing costs of other cancer therapies that provide more limited value. There is a better way, and ASTRO remains committed to working with the Agency and Congress to find it. Cancer patients deserve nothing less.

ASTRO appreciates the opportunity to comment on RO Model proposed rule. If you have any questions, please contact Anne Hubbard, Director of Health Policy at 703-839-7394 or Anne.Hubbard@ASTRO.org.

Sincerely,

Laura I. Thevenot

Chief Executive Officer

Laura Dawson, MD

Chair of the Board of Directors