

September 16, 2019

Ms. Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-5527-P
P.O. Box 8013
7500 Security Boulevard
Baltimore, MD 21244-8013

Submitted electronically: <http://www.regulations.gov>

Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures

Dear Administrator Verma:

The American Society for Radiation Oncology¹ (ASTRO) appreciates the opportunity to provide written comments on the “Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures” proposed rule as published in the Federal Register on July 18, 2019. ASTRO embraces the spirit and goals of the Medicare Access and CHIP Reauthorization Act (MACRA) and is committed to ensuring that radiation oncology can fully participate in an Advanced Alternative Payment Model (APM) that drives greater value in cancer care. This commitment is grounded in the belief that such a transition will lead to improved patient outcomes through the delivery of high quality, efficient care, as well as stable and predictable payment rates and reduced administrative burden.

While ASTRO appreciates CMS’ decision to move forward with an alternative payment model for radiation oncology and believes there are some positive elements in the proposed Radiation Oncology Model (RO Model), we are concerned that the proposal by the Agency falls short of meeting three key goals established by ASTRO for the successful development of an alternative payment model. They are:

1. The RO Model should rewards radiation oncologists for participation and performance in quality initiatives that improve the value of health care for patients.

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.

2. The RO Model should ensure fair, predictable payment for the radiation oncologist in both hospital and freestanding cancer clinics to protect cancer patients' access to care in all settings.
3. The RO Model should incentivize the appropriate use of cancer treatments that result in the highest quality of care and best patient outcomes.

We believe the RO Model, with significant modifications, could represent a meaningful and viable first step toward enabling the field of radiation oncology to participate in the evolving world of health care payment reform as initiated by MACRA. We are committed to working with the Agency to modify the model in such a way that it meets the aforementioned goals.

ASTRO appreciates that the Centers for Medicare and Medicaid Innovation Center (CMMI) has designed a model that is specific to radiation oncology services, recognizing the unique process of care associated with radiation therapy. We also recognize that the Agency has sought to align some of the proposal with the Radiation Oncology Alternative Payment Model concept paper that ASTRO submitted in April 2017². Key elements from that paper are found in the proposed rule, including the prospective payment; the episode trigger mechanism, timeline and clean period; establishment of distinct professional component and technical component payments; the inclusion of all modalities of treatment; and key quality measures elements. We thank the Agency for recognizing the efforts that ASTRO has put into the development of an alternative payment model for radiation oncology.

While we appreciate CMMI's recognition of ASTRO's efforts and the opportunity to collaborate on the development of an alternative payment model for radiation oncology, there are numerous significant issues with the proposed RO Model that will need to be addressed in order to ensure its success. According to the RO Model proposed rule, the model is designed to test whether prospective episode-based payments to radiation therapy centers for episodes of care "would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries." Unfortunately, we believe this premise is deeply flawed, as reducing payment will not improve quality, but rather jeopardize access to safe and effective radiation treatments by putting too much financial strain on radiation oncology practices that have no choice but to participate. **Instead, ASTRO recommends significant changes to the proposal that will incentivize the use of high quality, efficient radiation therapy treatments that drive value and generate savings for Medicare.** A summary of those key issues includes:

- **Mandatory Participation.** Requiring participation representing 40% of radiation oncology episodes goes much too far for an untested model. *Instead, CMS should launch the model as voluntary, then transition to mandatory on a limited basis, including opt-outs for low-volume practices and hardship exceptions.*
- **National Case Rates.** There are serious flaws in the calculation approach for the national case rates that would result in significant and unfair payment penalty for participants. We are concerned that the methodology fails to appropriately account for a range of complex clinical scenarios and average treatment costs for many clinics. *CMS must include some physician fee*

² Radiation Oncology Alternative Payment Model, April 27, 2017
https://www.astro.org/uploadedfiles/main_site/daily_practice/medicare_payment_initiatives/alternative_payment_model_program/content_pieces/roapm_description.pdf

schedule costs and ensure adequate payments for patients receiving standard of care multi-modality treatments, such as combination therapy for gynecological cancer.

- **Discount Factor and Efficiency Adjustment.** The proposed payment adjustments could result in significant cuts to all participants and would disproportionately harm “efficient” practices. *CMS should adjust the efficiency factor to avoid penalizing efficient practices and scale back the discount factors, which put at risk patient access by causing significant financial issues for such a capital expenditure intensive specialty.*
- **APM Incentive Payment.** CMS’ selective waiver of the 5% APM incentive payment on freestanding center technical payments undercuts the spirit and letter of MACRA’s intent of encouraging providers to assume risk and participate in APMs. *CMS should remove this waiver.*
- **Innovation.** Innovation in radiation oncology has contributed greatly to increased cure rates and reduced side effects from treatment. Yet, the RO Model does not adequately account for the next generation of advances in the delivery of radiation oncology. *CMS should pay for new technology at fee-for-service rates for a limited time and adopt a rate review mechanism for new service lines and upgrades.* It’s important that practices can continue to invest in innovations that provide clinical benefit for patients.
- **Burden.** The proposed RO Model would heap additional administrative tasks and costly requirements on already burdened radiation oncology practices that are required to participate in the model. *CMS should delay many of these requirements and rely heavily on recommendations from the radiation oncology community to ensure that only information that is most meaningful and least burdensome is collected.*

What follows is an in-depth review of each of the key aspects of the model. In this letter we seek to identify areas of agreement, and in situations where we believe there is a fundamental difference of opinion, we endeavor to provide potential solutions and proposed modifications.

Savings Target

ASTRO is greatly concerned that 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, and improved clinical outcomes.

The proposed RO Model estimates \$250-\$260 million in savings over a 5-year period to achieve CMS’ stated goal of 3 percent in overall savings. ASTRO’s analysis indicates that the savings generated by this proposed RO Model rely on significant cuts to RO Model participants totaling \$320 million over 5 years (see chart below). To secure savings, CMS is proposing a very complex and draconian payment methodology that cuts payments through an arbitrary discount factor, as well as the establishment of inaccurate national base rates and historical expenditure adjustments for each of the 17 cancer types, as well as an efficiency factor that cuts both efficient and inefficient practices. In addition, participants face serious cash flow problems due to the size and timing of payment withholds. There is virtually no opportunity for upside, as CMS has selectively waived a major portion of the 5% APM incentive payment bonus, enacted under MACRA to drive participation in new APMs.

	REDUCTION IN MEDICARE ALLOWED CHARGES TO RO MODEL PARTICIPANTS FOR BUNDLED SERVICES (millions)					
	2020	2021	2022	2023	2024	2020-2024
CMS VERSION	YR1	YR2	YR3	YR4	YR5	
CHANGE IN ALLOWED CHARGES	-\$54	-\$59	-\$64	-\$69	-\$74	-\$320 (-5.9%)
PROFESSIONAL	-\$9	-\$9	-\$10	-\$11	-\$12	-\$52
PC DISCOUNT	-\$7	-\$7	-\$7	-\$7	-\$7	-\$34
OTHER REDUCTIONS	-\$2	-\$3	-\$4	-\$5	-\$5	-\$18
TECHNICAL	-\$45	-\$49	-\$54	-\$58	-\$62	-\$268
TC DISCOUNT	-\$44	-\$45	-\$46	-\$46	-\$47	-\$228
OTHER REDUCTIONS	-\$1	-\$5	-\$8	-\$12	-\$15	-\$41

With virtually no positive incentives, direct cuts of this magnitude on clinics that have no choice but to participate are unwarranted and run afoul of the spirit and intent of MACRA and the move toward value-based payments. Unless the purpose of the RO Model is redirected away from direct payment cuts and toward realigned incentives, the model will fail, an opportunity will be lost and patient access will suffer. **ASTRO recommends that CMS consider an alternative approach to the RO Model that emphasizes incentivizing high-quality care, rather than penalizing those practices randomly selected to participate and putting them at a competitive disadvantage to their peers. ASTRO has worked to extensively identify these issues, none of which are insurmountable, and provide solutions.**

Mandatory Participation and Timing

According to the proposed rule, CMS will identify randomly selected Core Based Statistical Areas (CBSAs) for participation in the model. Based on a sample size large enough to achieve 3 percent Medicare savings, the RO Model is expected to include 40 percent of radiation oncology episodes in eligible geographic areas. While the proposed rule does not list specific CBSAs for participation in the model, the Agency does provide a simulation of the approach it will use to identify selected CBSAs. The CMS simulation identified 616 Physician Group Practices (PGPs) (325 of which are freestanding centers) and 541 Hospital Outpatient Departments (HOPDs) in the simulated selected CBSAs. These providers and suppliers delivered 39.7 percent of radiation episodes nationally, based on data from 2015-2017.

ASTRO has long-supported voluntary participation in a radiation oncology APM, and we are very concerned about launching a model that requires mandatory participation from over a third of radiation oncology practices at the outset. Requiring this 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. It has the potential to create competitive disadvantages for those participating in the model and, as currently designed, could impose potential financial hardships on practices that have significant fixed costs unmatched in medicine.

Additionally, we are concerned that the proposed model is not supported by Section 1115A of the Social Security Act, which authorizes CMMI to “test” a new payment and service delivery model. The proposed model exceeds the rational limits of CMMI’s authority in that it mandates

participation by radiation therapy providers in randomly selected zip codes,³ with only limited exclusions,⁴ for a five-year performance period. This expansive mandatory model goes far beyond any demonstration program that CMS has put into place thus far. The level of participation is beyond the scope of what is needed to test CMMI's objectives and appears to be driven solely by the desire to meet a three percent savings estimate.⁵

CMMI 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 CMMI's statutory authority. ASTRO believes that the proposed model is likely to decrease quality of care due to the mandatory nature of the model. First, while 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 would eliminate this safeguard. Given the significant change and rapid implementation of the model, forcing some unready practices to participate while at the same time prohibiting others that are well-prepared is problematic. For example, the payment structure (which involves withholds, discounts, and elimination of the APM incentive payment and other potential reductions of payment that are described throughout this comment) may cause practices to find that they are unable to offer certain services, invest in new technology or upgrade existing equipment.

Most importantly, beneficiaries will be negatively impacted by this model. By conscripting all radiation therapy providers within a randomly-selected zip code into the model, beneficiaries seeking radiation therapy services in those zip codes must also participate in the model or travel to a geographic area not included in the RO Model to seek care (regardless of their ability to do so).⁶ Thus, given the possible negative impact on quality of care, ASTRO believes that the RO Model as proposed exceeds CMMI's statutory authority and must be revised.

Furthermore, the Agency action creating the RO Model is arbitrary given that it fails to consider impacts on beneficiaries. Although the Social Security Act grants the agency an exemption from judicial review in many areas of CMMI Model design that would normally be subject to review under the Administrative Procedures Act (APA), we believe that the agency should strive to meet the threshold legal standard for all Agency actions, especially those that have such a vast consequence for providers and beneficiaries that will be subject to the Model. Agency action is considered arbitrary and capricious if the Agency “has relied on factors which Congress had not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.”

In failing to prioritize high quality care for Medicare Fee for Service (FFS) beneficiaries, the RO model conflicts with the explicit purpose of the program and CMS' own objectives—to promote high quality care and improve outcomes for Medicare beneficiaries.⁷ With regard to mandatory

³ 84 Fed. Reg. 34478, 34568.

⁴ 84 Fed. Reg. 34478, 34494.

⁵ 84 Fed. Reg. 34478, 34568.

⁶ 84 Fed. Reg. 34478, 34497.

⁷ 84 Fed. Reg. 34478, 34490 (July 18, 2019).

participation, CMS states that it believes requiring mandatory participation by radiation therapy providers and suppliers within randomly selected CBSAs will allow CMS to “have access to more complete evidence of the impact of the model.”⁸ Along with this justification, CMS offers as a point of comparison that the only voluntary prospective episode payment model tested to date by the Innovation Center—the Bundled Payments for Care Improvement Model or BPCI—only attracted 23 participants, of which 78 percent withdrew.⁹ CMS does not explain why it expects that the RO Model would have a similar voluntary participation rate as the BPCI model, or why it expects that a voluntary model would be less likely to result in complete evidence of the RO Model’s impact. This rationale also does not consider the potential disruption of care to vulnerable patients who will have no choice but to participate in the model due to their geographic location alone. These regulatory deficiencies render the regulatory action arbitrary and capricious. Because of these legal and policy insufficiencies, CMS must remove the mandatory nature of the RO model.

ASTRO urges CMS to initiate the model on a voluntary basis with little to no risk. 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.

Additionally, it is impossible to imagine that more than 1,000 practices will be notified in early November of their required participation and then start on January 1, 2020. As will be discussed further in our comments, the time, cost and effort burden of implementation on practices, particularly smaller practices, is substantial and CMS estimates of implementation burden are insufficient. Likewise, requirements for EHR vendors and systems needed to operate the model, will take time to develop, test, and implement. **Given these factors, ASTRO urges CMS to delay implementation until no sooner than July 1, 2020 to ensure participating practices have had adequate time to prepare for model implementation.**

Finally, CMS proposes that the model will be applicable in only the select CBSAs. Model exemptions are limited to states participating in other CMS waivers, US territories, ambulatory surgical centers, critical access hospitals, and PPS exempt cancer hospitals. There are no hardship exemptions and no opportunities for practices to opt-in to participation. ASTRO believes this is problematic for several reasons. First, this compelled participation has the potential to create a disadvantageous market dynamic between practices that are required to participate and those that are not, particularly if the Agency moves forward with the model payment construct as laid out in the proposed rule. **If the model is mandatory at the start or in the near future, ASTRO urges CMS to establish criteria by which small and/or rural practices that can demonstrate financial hardship can opt-out of the model. We also urge the Agency to establish an opportunity for practices to opt-into the model, once**

⁸ *Id.* at 34493.

⁹ *Id.*

recommended improvements have been made. Additionally, health systems may find that some of their practices are in the model while others are out, despite the fact that they operate under a single TIN. ASTRO urges CMS to make accommodations for health systems that have a centralized business office that would be significantly burdened if it had to comply with two distinct payment systems. **The Agency should allow multi-practice health systems the opportunity to opt-in or opt-out of the model on behalf of all of their practices. This is similar to the approach that the Agency has taken with regard to ACOs, in which participants are tied to the ACO based on a shared TIN.**

RO Model Participants

Medicare Beneficiaries

CMS proposes to include all traditional Medicare FFS beneficiaries who receive radiation therapy services for at least one identified cancer type in one of the selected CBSAs. The Agency also proposes to include any Medicare beneficiary participating in a clinical trial for radiation therapy services that are provided in either the experimental or control arms of a clinical trial.

ASTRO is concerned that the proposed model creates an unintended disadvantage for Medicare FFS beneficiaries in selected CBSAs. As discussed in subsequent sections of this comment letter, the model's design does not account for advances in new technology, new service lines or the need to upgrade existing equipment. This creates an imbalance between practices inside the model and those outside the model. This imbalance has the potential to result in some patient populations seeking care outside the model where they will have access to new technology and service lines provided by practices that are not participating in the model. Additionally, it could lead to access to care issues particularly for socio-economically disadvantaged patients who may not have the resources to seek care outside of a participating CBSA. This issue is further explored in subsequent sections entitled "New Service Lines and Equipment Replacement/Upgrade" and "New Technology". **ASTRO urges the Agency to carefully consider this issue and its impact on Medicare FFS beneficiary care.**

In the proposed rule, CMS proposes that patients treated by RO Model participants would pay 20 percent of the bundled payment amount that the practice or facility receives, rather than 20 percent of the amounts that Medicare would have paid under the Medicare Physician Fee Schedule (MPFS) and/or Hospital Outpatient Perspective Payment System (HOPPS) for the specific services that the patient received. This means that patients who receive fewer or lower-cost services than average for their type of cancer would pay more in cost-sharing than if they had received the same treatment in a non-participating region, whereas patients who receive more services than average would pay less in cost-sharing. Although CMS indicates that it believes cost-sharing will be "lower on average," and although many patients have supplemental insurance that will shield them from higher cost-sharing amounts, some patients may be harmed financially by this approach. **CMS should base patient cost-sharing on the lesser of (a) what the patient would have paid in cost-sharing under standard Medicare payment amounts for the specific services the patient received and (b) 20% of the bundled payment amount. This will remove any disincentive for a patient to obtain treatment from a participating practice and enable patients to share in the savings from using a bundled payment.**

Additionally, many Medicare FFS beneficiaries rely on some form of supplemental insurance, also known as Medigap, either through an employer or private insurance company to cover monthly Medicare Part B premiums and other cost sharing requirements. The proposed rule does not recognize or address the role of Medigap as a secondary payer. **ASTRO urges the Agency to provide clarification in the final rule regarding the role of these secondary payers and how they will be engaged as part of the claims processing and billing associated with implementing the model. We recommend that CMS follow current Coordination of Benefits rules and transmit no-pay claims for radiation therapy services under the RO Model as “paid” to supplemental insurers for secondary payment under FFS. This approach would allow for continuation of a long-established process between Medicare and secondary payers and address potential disruptions in the revenue cycle for providers in the model.**

Radiation Oncology Participants

CMS is proposing to require participation of three distinct types of Radiation Oncology (RO) participants: “Professional participants,” “Technical participants,” and “Dual participants”. Professional participants are Medicare-enrolled physician group practices, identified by a single Taxpayer Identification Number (TIN), that deliver only the professional component of radiation therapy services at either a freestanding radiation therapy center or a Hospital Outpatient Department (HOPD). A “Technical Participant” is a RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS certification number (CCN) or TIN, which furnishes only the technical component of RT services. A “dual participant” is a RO participant that furnishes both the professional component and technical component of an episode of RT services through a freestanding radiation therapy center, identified by a single TIN.

ASTRO supports these key participant distinctions and appreciates that CMS recognizes that radiation therapy services can be delivered at different sites of service. We believe this participant construct lends itself well to the establishment of separate professional and technical payment components.

In the proposed rule, CMS states that if a radiation oncology beneficiary changes their provider or the location where care is delivered after the State of Episode (SOE) claim has been paid, CMS will subtract the first episode payment paid to the RO participant from the FFS payments owed to the RO participant for services furnished to the beneficiary before the transition occurred. This occurs during the annual reconciliation process. The subsequent provider or supplier (whether or not they are a RO participant) will bill FFS for furnished radiation therapy services.

ASTRO appreciates that the CMS recognizes the potential for care to shift from one physician to another and from one site to another, however we believe it is important for the Agency to understand the full scope of scenarios in which this might happen. This is particularly important for cases in which a patient is treated with multiple modalities, such as external beam radiation therapy and brachytherapy. Appendix A includes common scenarios for the Agency to consider. **ASTRO urges the Agency to provide clarification regarding how these types of situations will be handled and appropriately reimbursed within the model. It is critical that standard**

of care multi-modality radiation treatments, such as for cervical and prostate cancer, are not inadvertently disincentivized under the model.

Episode Length and Trigger

CMS is proposing a 90-day episode of care that is triggered when two criteria are met: 1) there is an initial treatment planning service (submission of treatment planning codes 77261-77263) furnished by a Professional participant or Dual participant, and 2) at least one radiation treatment delivery service is furnished by a Technical participant or Dual participant within the following 28 days. This is based on claims data indicating that 99 percent of Medicare beneficiaries complete their course of radiation within 90 days of their initial treatment planning service. In order to disincentivize the extension of a treatment course beyond the 90-day episode window, CMS is establishing a clean period in which no episodes can be triggered that would last 28 days after the close of the previous episode. During the “clean period,” should a patient require radiation therapy services, then they would be billed in accordance with FFS billing rules.

ASTRO appreciates this approach to the establishment of an episode of care because it aligns well with the proposed model concept paper that was submitted to CMS by ASTRO in April 2017. **However, we would appreciate the Agency’s assurances that the 90-day episode of care includes multiple care episodes for bone and brain metastases. Based on our data analysis, we believe that the Agency is accounting for all services and multiple associated treatments, but we urge the Agency to clarify this in the final rule.**

Additionally, ASTRO appreciates the application of the 28-day window between treatment planning and treatment delivery. This ensures that most cases will fall within the 90-day episode of care. **ASTRO urges CMS to clarify how Medicare contractors will manage PC and TC claims after the 28-day period has passed. Would all TC claims (whether reported using the RO-APM’s specific HCPCS codes or FFS HCPCS codes) and the second episode payment PC claim be denied and then reconciled according to the Model’s incomplete episode policy? If so, this would create cash flow delays for participants. Would all TC claims in this scenario instead be paid under FFS and the initial episode PC payment be reconciled later?**

Finally, based on the language in the proposed rule, it is unclear whether the second and final payment installment is issued at the completion of treatment (days 2-89) or on the 90th day of the episode of care. According to a CMMI Radiation Oncology Model Listening Session held on Thursday, August 22nd, Agency staff indicated that a physician can submit the HCPCS code and modifier indicating the end of an episode any time prior to the 90th day. However, any additional services delivered between the end of the episode and the 90th day would not receive reimbursement. **We are in agreement with the proposed policy that would allow for final payment prior to the end of the 90-day episode and urge the Agency to clearly state its intent in the final rule. However, we also seek clarification that this no-pay policy does not apply to non-RO Model codes. For instance, if a patient is treated for metastasis to the adrenal gland, which is not included in the model, those payments would continue during this period.**

Included Services

CMS proposes that the model would include most radiation therapy services, including treatment planning; dose calculation; radiation physics and dosimetry, treatment devices, and special services; treatment delivery; and treatment management. The Agency proposes to exclude evaluation and management (E/M) services from the model; however, radiation oncologists can continue to bill these codes under Medicare FFS. Additionally, CMS is proposing to exclude low volume services from the model, including certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals.

ASTRO appreciates that CMS recognizes each of the distinct components in the delivery of radiation therapy. We are in agreement with the decision to exclude E/M services and these low volume therapies from the model. However, we urge the Agency to ensure that these services, particularly radiopharmaceuticals, are not included in the payment methodology.

Upon initial analysis of the national base rate, ASTRO found that the Yttrium-90 appeared in the payment data. Radioembolization (Y90) is a minimally invasive procedure that combines embolization and radiation therapy to treat liver cancer. Tiny glass or resin beads filled with the radioactive isotope yttrium Y-90 are placed inside the blood vessels that feed a tumor. The Y90 radiopharmaceutical is currently reported in Medicare with C2616 or Q3001. CMS explains in the proposed rule that they intended to exclude radiopharmaceuticals. **As such, we believe the Y90 radiopharmaceutical (reported with C2616/Q3001) was inadvertently included in the RO-APM model and should be removed.**

Additionally, ASTRO urges CMS to confirm that Radium-223 dichloride, recognized as A9606, is excluded from the model. Radium-223 is an FDA approved therapeutic radioisotope for the treatment of bone metastasis from hormone refractory prostate cancer. The isotope is delivered intravenously on a monthly basis for six months, far exceeding the 90-day episode of care.

The Agency considered excluding brachytherapy sources due to evidence that physicians sometimes contract with others to supply or administer brachytherapy sources or radioisotopes. CMS decided to include brachytherapy sources since hospitals are usually the purchasers of the radioactive elements that are generally furnished in HOPDs; however, any services delivered in an ASC would be excluded.

Section 1833(t)(2)(H) of the Social Security Act requires that brachytherapy source payments be made separately from professional services. Currently, brachytherapy sources are paid individual rates based on the type of radioactive source. Given the inherent differences in the types of sources needed for clinical care (including half-life, energy, dose rate, production in a medical reactor or cyclotron, and costs associated with manufacturing of the sources) the costs of each source can vary significantly and need to be ordered and made specifically for each patient. Billing for each patient would be based on the differences in isotopes, radioactive intensity, and the number of isotopes that are required for treatment of the individual patient. **ASTRO supports continued separate payment for brachytherapy sources. Given the smaller representation of brachytherapy (as a monotherapy and as a combination modality therapy) within radiation oncology, there are challenges in utilizing a mean episode cost approach for an infrequently utilized modality like brachytherapy, and the proposed**

methodology may not adequately account for the varying cost of the brachytherapy sources.

Finally, CMS includes brachytherapy insertion CPT codes 55920, 57155, 57156 and 58346 in Table 2 of the proposed rule, which includes a list of RO Model bundled HCPCS codes. However, only brachytherapy insertion code 55920 appears in the list of major procedure codes that are included in the data files that were issued with the proposed rule. **ASTRO urges the Agency to clarify whether the brachytherapy insertion codes are included in the model. ASTRO believes they should be included and has based its own analysis on the inclusion of those codes. Additionally, ASTRO urges CMS to provide clarification regarding how the Agency will handle a second claim for a case that has already received an episodic payment associated with a second physician who bills the brachytherapy insertion codes. Accommodations should be made to pay the insertion codes at the FFS rate when a second physician is involved to prevent cash flow issues that could result if the second claim were held up as part of the RO Model reconciliation process.**

Included Modalities

CMS proposes to include all modalities of treatment, including external beam therapy: three-dimensional conformal radiation therapy, intensity-modulated radiation therapy radiation therapy, stereotactic radiosurgery, stereotactic body radiation therapy radiation therapy, and proton beam therapy; intraoperative radiation therapy radiation therapy; image guided radiation therapy; and brachytherapy. **ASTRO supports the inclusion of these modalities of treatment.** However, we are concerned that the Agency does not address the acquisition of new modality service lines, equipment replacement/upgrades or new technology in the proposed rule.

New Service Lines and Equipment Replacement/Upgrades

Over the five-year term of the model many practices are likely to add new service lines and upgrade existing equipment, so they can continue to meet the clinical needs of cancer patients. New service lines are not new technology, but rather services that are new to a specific practice. Additionally, the useful life of most radiation therapy equipment, such as a linear accelerator, is seven years. Many practices participating in the model will need to either replace or upgrade equipment during the term of the model. The proposed RO Model payment methodology does not adequately account for these important investments.

Additionally, practices may want to add new service lines so they can provide patients with the most effective treatment close to home in their communities. For example, a practice may want to be able to deliver Stereotactic Radiosurgery (SRS) and/or hippocampal avoidance IMRT for whole brain, which have recently been shown in randomized controlled trials to benefit patients when compared to ‘standard’ whole brain treatment. If that practice does not have evidence of historical reference pricing that includes this service, then it is at a disadvantage, particularly given that the historical component of the payment rate is so heavily weighted (90 percent historical/10 percent national).

ASTRO urges the Agency to consider establishing a rate review mechanism by which practices seeking to adopt new services lines or replace/upgrade existing equipment can submit an application for a rate review that would allow practices to make the argument for rate modifications during the term of the model. Applications would be reviewed by a

panel of radiation oncology experts recommended by stakeholder groups, such as ASTRO, as well as CMS staff experts. Applications should be reviewed and considered on a yearly basis, six-months prior to the start of each performance year, with decisions issued with annual payment rate update notices.

New Technology and Innovation

Radiation therapy has been utilized to deliver life-saving cancer treatments for well over 100 years. It is a tried and true technique that continues to evolve over time yielding safer and more effective cancer treatments. Advances in technology, particularly over the last quarter century, have allowed radiation oncologists to more precisely map the location of cancer, delivering higher, more effective doses of radiation that limit the exposure to normal tissue. To ensure the continued growth and adoption of new technology in the field of radiation oncology, **ASTRO urges CMS to pay FFS rates for any new technology identified by a new CPT code or new technology code during the term of the model. This will ensure the continued growth and adoption of new innovations that improve patient care.**

Proton Beam Therapy

CMS invites comment on its proposal to include proton beam therapy in the RO Model. The Agency sites reports from Institute for Clinical and Economic Review (ICER) and the Medicare Patient Advisory Commission (MedPAC) in which both groups purport that proton beam therapy is of lower value when compared with other forms of radiation therapy. ASTRO wishes to point out that this blanket statement is not applicable to all disease sites. While ASTRO agrees with and actively works to address inappropriate utilization of services that do not benefit patient care, PBT can serve as an effective, evidence-based treatment for a specific group of clinical indications, such as ocular tumors, chordomas, chondrosarcomas, primary or metastatic tumors of the spine, hepatocellular cancer, and certain malignant and benign primary CNS tumors, just to name a few¹⁰.

The Agency proposes to exclude proton beam therapy from the included modalities in instances where a beneficiary is participating in a federally funded, multi-institutional, randomized control clinical trial for proton beam therapy so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered. **ASTRO supports this proposed exclusion, but believes it is too strict and potentially limits opportunities that would benefit Medicare FFS beneficiaries while advancing the evidence base.**

Cancer Types

CMS is proposing to include 17 cancer types in the model, including Anal, Bladder, Bone Metastases, Brain Metastases, Breast, Cervical, CNS, Colorectal, Head and Neck, Kidney, Liver, Lung, Lymphoma, Pancreatic, Prostate, Upper GI, and Uterine. Additionally, the Agency states that it will notify RO Participants of any addition or removal of these proposed cancer types “per the CMS standard process for announcing coding changes and update the list on the RO Model website no later than 30 days prior to each performance year.”

ASTRO appreciates that CMS wants to include as many cancer diseases sites as possible. This

¹⁰ ASTRO Proton Beam Model Policy

ensures that the broadest population of patients can benefit from the model, once improvements are made, and it also reduces the administrative burden associated with operationalizing a model for a few key cancer sites and not others. However, as described below, we do have concerns regarding the application of the model to patients who present with cancer and require radiation treatment to multiple disease sites. **ASTRO urges the Agency to provide clarification regarding the “standard process for announcing code changes.” Will proposals to add or remove disease sites involve a comment period to allow for analysis and stakeholder input?**

Multiple Disease Sites

CMS proposes to pay one bundled rate regardless of whether the patient is seeking radiation treatment for one cancer type or concurrent treatments for multiple cancer types, including simultaneous treatments to primary disease sites and areas of symptomatic or oligometastatic disease. ASTRO appreciates that the frequency of concurrent treatments for multiple cancer types is limited. However, when these cases do occur, they are frequently more complex and costly. ASTRO’s own analysis bears out CMS’ assertion that these cases are infrequent. **We urge the Agency to monitor the frequency and cost of care associated with multiple disease site cases in order to determine if the payment methodology should be modified in future years.**

Episode Payment Construct

CMS is proposing that each episode would have corresponding Professional Component (PC) and Technical Component (TC) payment amounts. These amounts represent the totals of calculated payment amounts for the professional and technical services of the radiation treatment furnished over the 90-day episode of care. The Agency proposes to calculate the payment amounts for the PC and the TC of each episode as the product of: 1) the OPPS or PFS national payment rates for each radiation therapy service included in the RO Model multiplied by 2) the volume of each professional and technical radiation therapy service included on a paid claim line during an episode of care.

ASTRO supports this proposal, as it aligns with the recommendations made in ASTRO’s April 2017 concept paper. The establishment of separate PC and TC payments recognizes the distinct physician work and practice expense components associated with the delivery of radiation therapy services.

Site Neutral Test and National Base Rate Development

The RO Model proposal includes a “site neutral test” that would establish a common payment amount for services regardless of where they are furnished. The Agency believes this 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 is proposing to utilize historical HOPD episode payment data as the foundation for the development of National Base Rates for the PC and TC payment for each of the 17 disease sites. Episodes used to develop the national base rate include 1) episodes initiated between 2015-2017; 2) episodes attributed to a HOPD; and 3) during an episode, the majority of the technical services were provided in a HOPD. The Agency is proposing 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, than those under the Medicare Physician Fee Schedule (MPFS).

ASTRO supports the proposal of a site neutral test and appreciates the Agency's commitment to providing participants with stable rates. However, we are concerned with the Agency's decision to establish the site neutral test based on OPPS data alone.

ASTRO's analysis of the proposed National Base Rates payment rates indicates that it does not adequately account for the cost of care involving services delivered in the freestanding setting, particularly professional services. Our analysis indicates that only 64 percent of all radiation therapy episodes during 2015-2017 are used for the proposed case rates. Per the chart below, the prostate cancer National Base Rate is based on just 51 percent of total episodes during the historical period. This is in comparison to other cancer types, such as liver cancer which is based on 82 percent of total episodes during the historical period. The chart below demonstrates these distinctions by cancer type.

CANCER_TYPE	All Episodes	HOPD-Tech Provider Episodes [BASE RATE EPISODES]	Non HOPD-Tech Provider Episodes	SHR OF EPISODES THAT ARE USED FOR BASE RATES
Breast Cancer	113,262	74,741	38,521	66%
Lung Cancer	99,517	69,799	29,718	70%
Prostate Cancer	91,551	46,917	44,634	51%
Bone Metastases	48,873	28,254	20,619	58%
Brain Metastases	32,086	22,065	10,021	69%
Head and Neck Cancer	29,636	19,416	10,220	66%
Lymphoma	17,425	11,748	5,677	67%
Colorectal Cancer	16,099	10,982	5,117	68%
Upper GI Cancer	14,750	9,791	4,959	66%
Uterine Cancer	14,678	10,746	3,932	73%
CNS Tumor	10,075	7,311	2,764	73%
Bladder Cancer	7,598	4,727	2,871	62%
Pancreatic Cancer	6,970	5,009	1,961	72%
Liver Cancer	5,273	4,342	931	82%
Anal Cancer	4,940	3,155	1,785	64%
Cervical Cancer	2,946	2,087	859	71%
Kidney Cancer	2,309	1,827	482	79%
TOTAL	517,988	332,917	185,071	64%

The value of professional services is derived the same way for both the hospital and freestanding setting. Additionally, despite CMS' assertion regarding rate stability in the MPFS, the rates for treatment planning, treatment management and other professional services codes have remained stable during the 2015-2017 historical period. Therefore, ASTRO is urging CMS to blend the historical PFS and OPPS rates for the PC of each

cancer type to establish a more accurate payment rate. We believe that a blend more accurately accounts for the professional work taking place in both sites of service.

Furthermore, it is apparent in our analysis of the data points used to formulate the National Base Rate that the Agency has inappropriately included incomplete and palliative care cases that distort the true cost of care. ASTRO urges the Agency to adopt business rules that can be applied to rectify the inclusion of incomplete and palliative care cases (Appendix B). The business rules are designed to remove those cases that are palliative in nature, which tend to involve specific modalities of treatment with ten or fewer fractions, as well as standards of care (e.g. 10 fractions of 3-Dimensional radiation therapy does not represent a standard of care for prostate cancer). The data associated with palliative care cases has been aggregated to establish a separate palliative care episode that is further discussed below. Finally, the business rules correct the significant undervaluation of radiation oncology services as constructed the National Base Rates. This is particularly evident in the discussion regarding the efficiency factor, which, despite its intention, puts even the most efficient practices at financial risk under the RO Model.

In addition to removing palliative care cases, the rules also remove the use of C2616 for Yttrium or Y90, which, as discussed above, is considered a radiopharmaceutical by the Agency. **C2616 was incorrectly included in proposed episode rates for bone metastases, brain metastases, breast cancer, colorectal cancer, liver cancer, and pancreatic cancer.**

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 concerns about the HOPPS 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 OPPS 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. This is particularly acute for the delivery of brachytherapy for the treatment of cervical cancer. It will be critical as this model evolves to continue to monitor how the OPPS methodology impacts the TC payment rates associated with the model.

Cancer Type Specific Payment Methodology Concerns and Business Rules

Cervical Cancer

The standard of care for the nonsurgical curative management of cervical cancer includes concurrent chemotherapy with external beam radiation therapy (EBRT) and brachytherapy. Brachytherapy is a surgical procedure to introduce radioactive elements directly into or adjacent to the cancerous tumor. Patients who receive this specific combination of treatment experience high quality outcomes, including longer survival times and lower mortality rates. The

effectiveness of this multimodality approach to cervical cancer hinges on evidence that optimal treatment is achieved when all chemotherapy and radiation therapy (both external therapy and brachytherapy) is completed within 56 days or 8 weeks.¹¹ Exceeding this period results in decreased local tumor control and survival for the patient with each day of delay¹².

Delivery of brachytherapy for cervical cancer results in control rates as high as 100 percent for stage IB, 96 percent for stage IIB, and 86 percent for stage IIIB patients, yet an analysis of the National Cancer Data Base indicated that of 7,654 patients diagnosed with curative cervical cancer, including the use of brachytherapy, declined from 98 percent to 86 percent between 2004 and 2011. The median survival time was 70.9 months for those treated with brachytherapy compared to 47.1 months for those treated with other modalities.¹³

In the United States, the most commonly used regimens are 45Gy EBRT to the pelvis (possibly with a sidewall boost) with concurrent cisplatin-based chemotherapy and either 5.5 Gy per fraction for five fractions (for patients treated with concurrent chemotherapy who have had either a complete response or have <4 cm of residual disease) or 6 Gy for five fractions (for patients with tumors >4 cm after EBRT).¹⁴

CMS proposes a PC payment of \$3,779 and a TC payment of \$16,955 for cervical cancer cases. Based on the CMS data files issued in with the proposed rule, of the 2,946 episodes that occurred between 2015-2017, only 629 of the episodes were treated with combination EBRT and brachytherapy--the standard of care described above. For these 629 episodes that were provided with guideline concordant care, the average PC allowed charges were \$4,932 and the average TC allowed charges were \$20,315, significantly more than the proposed RO Model episode PC and TC rates, which makes sense given the multiple modalities involved.

Additionally, of the 629 episodes, only 108 involved one physician, who provided the full course of treatment. All of the other episodes involved two different physicians. Additionally, a data analysis examining site of service shifts demonstrates that, of all cancer types included in the RO model, cervical cancer has the greatest number of site of service shifts from freestanding to HOPD and vice versa.

Given these nuances associated with the delivery of radiation therapy for cervical cancer and the ASTRO-provided empirical data demonstrating how the C-APC methodology undervalues treatment for cervical cancer, ASTRO urges CMS to establish separate payment episodes for each physician involved in the delivery of care for the treatment of

¹¹ Song MD, Suisui, et al. (January 15, 2013) The Effect of Treatment Time in Locally Advanced Cervical Cancer in the Era of Concurrent Chemoradiotherapy. *Cancer*, 325-331.

¹² Petereit MD, Daniel G., et al. (1995) The Adverse Effect of Treatment Prolongation in Cervical Carcinoma. *International Journal of Radiation Oncology Biology Physics*, Volume 32, No. 5, 1995, 1301-1307.

¹³ Petereit MD, Daniel G., et al. (March 20, 2015) Brachytherapy: Where Has It Gone? *Journal of Clinical Oncology*, Volume 33, No. 9, 980-983.

¹⁴ National Comprehensive Cancer Network. Cervical Cancer (Version 1.2017). <https://www.tri-kobe.org/nccn/guideline/gynecological/english/cervical.pdf> Accessed March 21, 2018.

cervical cancer¹⁵, particularly considering that frequently there are two physicians involved in the delivery of care and multiple sites of service. We believe this is solution is an important opportunity to ensure that patients are receiving the most appropriate care that aligns with guidelines, which will lead to greater survival benefit for cervical cancer patients.

Liver Cancer

Liver cancer is a very complex disease that frequently presents as hepatocellular carcinoma. Treatment options frequently include radioembolization (RE), which involves injecting small beads or microspheres that have a radioactive isotope (Y-90) attached to them into the hepatic artery. The radiation travels a short distance, so its effects are mainly limited to the tumor. Delivery of the radioactive isotope is frequently managed by both a radiation oncologist and an interventional radiologist, who are both involved in treatment planning and delivery. Additionally, these cases are frequently delivered in the HOPD setting.

The RO Model payment mechanism would likely involve a high frequency of cases that would trigger an incomplete episode, because one physician is involved in the planning and the other is involved in the delivery. Additionally, we understand that for institutions where the radiation oncologist triggers the episode, there will likely be a separate FFS payment to the interventional radiologist for their work. This puts the patient in the position of paying 20 percent of the bundle, 20 percent of the FFS work delivered by the interventional radiologist, and 20 percent of the radioisotope, potentially a significant financial burden and more than what the patient would be responsible for under a straight FFS payment methodology. **Given these rather unique and confounding factors compared other cancer types, ASTRO urges the Agency to remove liver cancer and thus the following ICD codes from the list of cancer types included in the model:**

- **IDC9: 155.xx, 156.0x, 156.1x, 156.2x, 156.8x, 156.9x**
- **ICD10: includes C22.xx, C23.xx, C24.xx**

Secondary Diagnosis Episode of Care

As previously mentioned, ASTRO recommends that CMS remove the palliative care episodes from the specific cancer type episodes of care and establish a separate Secondary Diagnosis episode for all disease sites, excluding bone and brain metastases. The PC payment for an episode of palliative care would be \$1,503 and the TC payment would be \$8,330. We believe that by pulling these cases out of the other disease sites we are more accurately accounting for the cost of care within each distinct episode, this is particularly important for lung cancer. Our analysis of the episodes included in the CMS case file indicated that each of the cancer types included a percentage of palliative care cases, lung had the most significant amount at 47 percent of all cases between 2017-2019.

To conclude our comments on the National Base Rates, the chart below details the CMS proposed payment rates in comparison with ASTRO's recommended payment rates, including:

¹⁵ ASTRO letter re: Comprehensive Ambulatory Payment Classification Methodology. March 11, 2019

- Application of the business rules across both the PC and TC payment rates,
- Blended PFS/HOPPS data for the PC payment rates,
- Separate payment episodes for each physician involved in cervical cancer,
- And, newly established Secondary Disease Sites episode.

	Professional Component		Technical Component	
CANCER_TYPE	CMS VERSION	ASTRO VERSION	CMS VERSION	ASTRO VERSION
Anal Cancer	\$2,968	\$3,125	\$16,010	\$16,451
Bladder Cancer	\$2,637	\$3,123	\$12,553	\$14,387
Bone Metastases	\$1,372	\$1,443	\$5,561	\$5,510
Brain Metastases	\$1,566	\$1,591	\$9,217	\$9,150
Breast Cancer	\$2,075	\$2,184	\$9,739	\$9,695
CNS Tumor	\$2,463	\$2,534	\$14,194	\$14,163
Cervical Cancer	\$3,780	\$4,071	\$16,944	\$18,168
Colorectal Cancer	\$2,369	\$2,703	\$11,590	\$12,753
Head and Neck Cancer	\$2,946	\$3,122	\$16,710	\$17,226
Kidney Cancer	\$1,551	\$1,570	\$7,659	\$7,593
Lung Cancer	\$2,155	\$2,855	\$11,451	\$13,657
Lymphoma	\$1,662	\$1,720	\$7,444	\$7,406
Pancreatic Cancer	\$2,380	\$2,466	\$13,074	\$13,003
Prostate Cancer	\$3,228	\$3,777	\$19,876	\$21,331
Upper GI Cancer	\$2,499	\$2,799	\$12,615	\$13,883
Uterine Cancer	\$2,376	\$2,538	\$11,223	\$11,566
Secondary Diagnoses	NA	\$1,503	NA	\$8,330

Case Mix Adjustment, Historical Adjustment and Efficiency Factor

The Agency proposes to adjust the national base rates to account for RO participant's case mix, historical experience, and efficiency. ASTRO appreciates that the payment methodology places a significant weight on the value of historical payment rates that are specific to each practice. We believe this will help many practices as they transition into the model. However, it is important that each of these components be calculated so that they appropriately account for practice experience that is recognized in the final cancer type payment rates, including the above modification and business rules.

CMS has proposed a methodology for the calculation of a predicted payment, which incorporates the regression model generated coefficients to predict payments under the FFS payment system

for an episode of care as a function of the characteristics of the RO participant's beneficiary population. The proposal also discusses the calculation of an expected payment, which uses the Winsorized episode payment made for each cancer type in the national beneficiary profile without accounting for the case mix adjustment. However, CMS does not provide any details on the range of predicted and expected payments for an RO participant, or examples of how it would be calculated for a practice. It is ASTRO's understanding that these payments are based on National Base Rate data. These inputs could significantly impact a RO participant's payment adjustments. **ASTRO urges CMS to provide details regarding the calculations associated with the predicted and expected payments so that practices can fully understand the overall impact on the RO Model's payment methodology.**

The Agency proposes to establish a Case Mix Adjustment 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 proposed to be applied to the PC and TC component for each disease site. To do this, the Agency proposes to measure 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.

ASTRO does not agree with the Agency's proposal to establish a national beneficiary profile based solely on the HOPD setting. This proposal disregards the differences in case mix between freestanding and hospital-based practices, which can vary significantly. Based on our analysis below, the application of the business rules and the inclusion of the MPFS data yields a predictive value closer to 1, indicating that the case mix variables would be more accurately attributed to each cancer type. **ASTRO urges the Agency to adopt the business rules and use a blended MPFS/OPPS methodology to accurately allocate the Case Mix Adjustment in the RO Model payment methodology.**

	PROFESSIONAL COMPONENT		TECHNICAL COMPONENT	
CANCER_TYPE	CMS VERSION	NEW BUSINESS RULES (ALL EPISODES)	CMS VERSION	NEW BUSINESS RULES (ALL EPISODES)
Anal Cancer	1.01	1.00	0.96	1.00
Bladder Cancer	1.13	1.01	1.07	1.01
Bone Metastases	1.16	1.01	1.03	1.01
Brain Metastases	0.88	0.99	0.75	0.99
Breast Cancer	1.05	0.99	1.03	1.00
CNS Tumor	0.93	1.00	0.90	1.00
Cervical Cancer	0.99	1.00	0.94	1.00
Colorectal Cancer	0.99	0.99	0.95	1.00
Head and Neck Cancer	1.05	1.00	1.02	1.00
Kidney Cancer	0.75	0.99	0.71	1.00
Lung Cancer/Curative	0.94	0.99	0.87	0.97
Lung Cancer/Palliative	NA	0.98	NA	0.98
Lymphoma	1.01	0.99	0.98	0.99
Pancreatic Cancer	0.94	0.98	0.88	1.00
Prostate Cancer	1.41	1.00	1.32	1.00
Upper GI Cancer	0.99	0.97	0.94	1.00
Uterine Cancer	0.94	0.99	0.88	1.00
Other Palliative		0.98		0.98

CMS also proposes to apply a historical experience adjustment that is calculated for the PC and the TC based on episodes attributed to a RO participant's practice. The methodology for the historical experience uses Winsorization to cap episode payments. **ASTRO urges the Agency to apply the same business rules to the historical rates that we recommend applying to the National Base Rates in the section above.** This ensures that the historical rates align with the National Base Rates, which yield more accurate payment rates.

Finally, the Agency proposes to apply an Efficiency Factor 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 appreciates the intent of the Efficiency Factor; however, we believe it falls short and potentially harms practices that have already demonstrated high efficiency. As demonstrated below, the Efficiency Factor does not protect efficient practices from experiencing payment cuts under the RO Model. **ASTRO urges CMS to modify the Efficiency Factor so that it effectively protects efficient practices from any financial instability associated with the transition to value based payment. This is particularly important given that many of these practices are already providing efficient, high quality care.**

EFFICIENCY FACTOR ANALYSIS				
EFFICIENCY FACTOR ANALYSIS PY1				
	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%

Discounts and Withholds

The Agency proposes a Discount Factor of 4 percent for the PC and 5 percent for the TC. CMS believes that the proposed Discount Factors strike a balance between creating savings for Medicare, while not creating substantial financial burden on radiation oncology participants. ASTRO disagrees that the discount factors strike any such balance.

CMS also proposes an incorrect payment withhold, and either a quality withhold, or a patient experience withhold, depending on the type of component (PC or TC) furnished during the episode. The 2 percent incorrect payment withhold reserves money for purposes of reconciling duplicate radiation therapy services and incomplete episodes during the reconciliation process.

The 2 percent quality withhold for the professional component allows the model to include quality measure results as a factor in determining payment to model participants. Professional and dual participants would be able to earn back up to the 2 percent withhold amount each year based on their aggregate quality score (AQS). A separate 1 percent patient experience withhold would be applied, starting in 2022, to the technical component to account for patient experience in the model through the implementation of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey for Radiation Therapy.

The discount factors represent a significant and excessive cut. Additionally, combined with the withholds, they have the potential to put many practices at financial risk, particularly those with thin operating margins. ASTRO urges the Agency to reduce the discount factors to 3 percent for both the PC and the TC payment. Additionally, we urge CMS to forward fund the withholds, so that revenues are not tied up during the 20-month post performance period reconciliation and true up process. This is further addressed in the subsequent section on the reconciliation process.

The chart below demonstrates the overall impact were CMS to implement ASTRO's recommended changes to the payment methodology. The recommended modifications yield the Agency \$150 million in savings over the five-year period through reductions in allowed charges to participants of \$192 million. While we understand that this amount could change if the

Agency decides to pursue a phased in approach to the mandatory requirement or establish voluntary participation, we believe that the combination of a more appropriate payment methodology in combination with voluntary participation would make the RO Model more attractive to radiation oncology practices. **ASTRO urges the Agency to accept all of the recommended payment methodology modifications.**

	REDUCTION IN MEDICARE ALLOWED CHARGES TO RO MODEL PARTICIPANTS FOR BUNDLED SERVICES (millions)					
	2020	2021	2022	2023	2024	2020-2024
ASTRO Recommendation	YR1	YR2	YR3	YR4	YR5	
CHANGE IN ALLOWED CHARGES	-\$20	-\$23	-\$26	-\$30	-\$33	-\$132 (-2.4%)
PROFESSIONAL	-\$4	-\$5	-\$5	-\$5	-\$6	-\$25
PC DISCOUNT	-\$5	-\$5	-\$5	-\$5	-\$5	-\$26
OTHER REDUCTIONS	\$1	\$1	\$0	\$0	-\$1	\$1
TECHNICAL	-\$16	-\$18	-\$21	-\$24	-\$27	-\$106
TC DISCOUNT	-\$27	-\$27	-\$28	-\$28	-\$29	-\$139
OTHER REDUCTIONS	\$11	\$9	\$7	\$4	\$2	\$32

Recognition of 2020 and 2021 MIPS Performance Bonus Payments

According to the proposed rule and confirmed by CMS staff on the August 22nd CMMI Listening Session, the Agency proposes to omit Merit Based Incentive Payment System (MIPS) bonus payments from the historical payment methodology for practices who have successfully complied with MIPS reporting requirements in payment years 2020 and 2021, based on performance years 2018 and 2019. This is disappointing particularly given the amount of time and resources that these practices have put into participating in the MIPS program. This decision further penalizes participants that are randomly selected. **ASTRO strongly urges CMS to honor its commitment to MIPS practices that have operated in good faith and complied with program requirements by issuing the MIPS bonus payments in the payment methodology for 2020 and 2021.**

Low Volume Practices

According to the proposed rule, if a HOPD or Freestanding Radiation Therapy Center provides fewer than 60 attributed episodes during the 2015-2017 period, the radiation oncology participant's participant-specific professional episode payment and technical episode payment amounts are proposed to equal the trended national base rates in the first performance year. This would continue in year 2 should the participant not achieve the 60-episode threshold, but a case mix adjustment would be applied to the national case rate. In performance year 3, if the participant continues to have fewer than 60 episodes, then the Agency will reevaluate.

ASTRO appreciates this gradual approach to establishing payment rates for low volume practices. These are typically small or new practices that are likely to gradually ramp up services over the life of the model.

Quality Measures

CMS proposes to adopt 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. ASTRO appreciates the Agency’s holistic view of patient care in including the first four quality measures.

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
CAHPS Cancer Survey for RT	Patient-Reported	N/A	PYs 3-5
Clinical Data Elements	Beneficiary-Level	PYs 1-5	TBD

The proposed rule does not specify which benchmarks and collection types the Agency is using for these measures. **ASTRO recommends that MIPS benchmarks and collection types be used to ease transition into the RO APM and align quality reporting programs. Without information on how data will be submitted to CMS for this model, we urge CMS to consider allowing practices to use relevant third parties for data collection and reporting, as it does in other quality reporting programs.**

ASTRO notes in the chart below that for two of the quality measures, at least one of the 2019 MIPS benchmarks is topped out, which means that if participants chose to submit data using that collection type, they will not receive the full 10 points, putting them at a disadvantage in the overall scoring.

Quality Measure	MIPS Benchmark Collection Type(s)	2019 MIPS Benchmark
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Oncology: Medical and Radiation – Plan of Care for Pain (NQF41 #0383; CMS Quality ID #144)	Registry	Not topped out
Preventative Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality Data ID #134)	Claims EHR Registry	Claims is topped out
Advanced Care Plan (NQF #0326; CMS Quality ID #047)	Claims Registry	Claims is topped out
Treatment Summary Communication – Radiation Oncology	Registry	Currently has no benchmark

ASTRO further notes that the Oncology: Medical and Radiation – Plan of care for Pain (NQF41 #0383; CMS Quality ID #144) measure was changed for the 2019 MIPS performance year from those who report all pain to those who report moderate or severe pain. However, the measure steward is currently working to revise the measure back to the 2018 specifications (all pain). The proposed rule states that participants must use the “most recent” measure, which indicates reporting for moderate or severe pain (2019 specifications); however, the provided measure specifications are for the 2018 measure. **ASTRO urges the Agency to clarify that 2018 specifications will be used in 2020, which includes all patients.**

The Treatment Summary Communication – Radiation Oncology measure is currently in use in the QOPI Qualified Clinical Data Registry (QCDR). When the measure was submitted during the 2019 (QCDR) self-nomination, the CMS/PIMMS team responded that the measure would only be approved if the timeframe was changed from 4 weeks to 2 weeks. There was no evidence or measure testing presented to justify this change. The measure specifications included in this proposed rule reference the original version with the 4-week time frame. **ASTRO appreciates the Agency’s desire to use the original specifications but requests that CMS align the APM measures across all CMS reporting programs. We support CMS’ ongoing work to streamline programs and quality measures where possible and request that all programs use the original specifications to avoid physician burden and confusion. We are separately commenting on this issue in the Medicare Physician Fee Schedule and urge alignment around the four week timeframe across all of CMS’ quality programs.**

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. We believe that it could be an inappropriate cohort comparison, if the Agency is planning on utilizing the MIPS benchmarks. **If CMS insists on utilizing this measure, we recommend that CMS either reclassify this measure as pay for reporting until a radiation oncology benchmark can be set and used in future payment years or consider an alternate measure.**

CMS notes that Advanced APMs must include at least one outcomes measure. The Agency concedes that currently there is no appropriate outcomes measures for radiation oncology, thus the requirement does not apply. However, if a relevant outcome measure becomes available the Agency will consider it for future use. **ASTRO is pleased that the Agency acknowledges for the lack of directly-relevant outcome measures for radiation oncology, and we look forward to working with the Agency to explore future development of outcome measures.**

CAHPS Cancer Care Survey

In addition to the quality measures described above, CMS also proposes to incorporate selected patient experience measures based on the CAHPS Cancer Care Survey for Radiation Therapy. For Dual participants and Technical participants, results from these patient experience measures will be incorporated into the AQS starting in performance year 3 and applied to the patient experience withhold described in the payment methodology section. **ASTRO is pleased that CMS is including the patient perspective on those care elements outside of treatment; however, we request clarification on who will administer the survey and when the survey will be deployed in relation to when the results are incorporated into the AQS.** Based on our understanding of other CAHPS models, the paper version is cumbersome and not completed by many patients due to the time lag and the lack of practice name included on the survey itself.

In future rulemaking, CMS plans to propose a set of patient experience measures based on the CAHPS Cancer Care Survey for radiation therapy, which would be included in the AQS as pay-for-performance measures beginning in performance year 3. ASTRO is aware that this particular survey is currently undergoing revision and will not be incorporated into the AQS until year 3, therefore, CMS will not have data with which to propose measures until after year 3. Will these measures be based on benchmarks, and if so, how will the benchmarks be developed? **We recommend CMS engage ASTRO and other radiation oncology stakeholders in the development of these measures and delay this implementation until at least performance year 4.**

Quality Measure Data Collection Process

CMS is proposing to require that Professional and Dual participants report aggregated quality measure data, instead of beneficiary-level quality measure data. **ASTRO appreciates the intent of reducing reporting burden in this manner; however, we request clarification on how CMS will implement this requirement to ensure it does so.** What collection types and reporting mechanisms will CMS allow? Will participants keep track internally and submit into a portal? Will the collection and submission types mimic MIPS, or will they be unique to the RO Model?

Additionally, the Agency is proposing to require that data be reported for all applicable patients (not just Medicare beneficiaries or the 17 disease sites covered by the model) based on the numerator and denominator specifications for each measure. CMS believes that collecting data for all patients who meet the denominator specifications for each measure from a Professional participant or Dual participant, and not just Medicare FFS beneficiaries, is appropriate because it is consistent with the applicable measure specifications, and any segmentation to solely the Medicare FFS populations would be inconsistent with the measure and add a substantial reporting burden to RO participants. **ASTRO disagrees and believes that reporting for all patients is overly burdensome and essentially an unfunded mandate given the amount of**

time and effort that will be required to not only submit the data points but also to provide and manage beneficiary notification and data collection opt-out options. Additionally, ASTRO is concerned that requiring the reporting of data elements for patients not participating in a Medicare program could require significant administrative burdens on RO participants in order to comply with HIPAA. **ASTRO urges CMS to modify the quality reporting requirement by limiting it to just those patients who are participating in the RO Model.**

Similar to the MIPS program, the RO Model will not score measures for a given Professional participant or Dual participant that does not have at least 20 applicable cases according to each measure's specifications. If measures do not have at least 20 applicable cases for the participant, CMS would not require the measures to be reported. **ASTRO appreciates the Agency aligning the RO Model with other quality reporting programs.**

Finally, CMS proposes to provide Professional participants and Dual participants with a mechanism to input quality measure data, including a secure portal for data submission. **ASTRO requests additional information on the reporting mechanism and urges CMS to utilize the same data collection and reporting tools that are available to clinicians participating in MIPS.** Additionally, ASTRO is concerned that Professional participants who utilize hospital-based reporting systems may encounter barriers to reporting measures due to the fact that there is no requirement that hospitals modify systems to support RO Model quality measures reporting. **ASTRO seeks guidance from the Agency on what measures will be taken to compel hospitals to adjust systems to ensure a smooth measure reporting process for Professional participants.**

Proposed Clinical Data Collection

In addition to collecting quality measure data, CMS is also proposing to collect clinical information on certain Medicare beneficiaries from Professional and Dual participants. On a pay-for-reporting basis, the Agency is proposing that both Professional and Dual participants report basic clinical information, not available on claims or captured in quality measures, on Medicare FFS beneficiaries treated for prostate, breast, lung, bone metastases, and brain metastases. CMS proposes to use the data to support clinical monitoring and evaluation of the RO Model. The Agency will determine specific data elements and reporting standards prior to the start of the Model.

It is difficult to comment on this section since it is not fully defined. **Based on what information is provided, we believe that the requirement that participants must report on 95 percent of their Medicare patients meeting the denominator specifications (i.e., being treated for the five categories) is overly burdensome.** We understand the necessity for extra data, and appreciate a more well-rounded view of the patient; however, **we recommend phasing in this requirement over several years to give participants time to address any difficulties in reporting. We believe that much of this data can be found in SEER Incidence Data¹⁶ and we strongly recommend CMS reduce or eliminate this requirement.**

¹⁶ The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (NCI) is an authoritative source of information on cancer incidence and survival in the United States. The SEER Program registries routinely collect data on patient demographics, primary tumor site, tumor morphology and stage at diagnosis, first course of treatment, and follow-up for vital status.

Additionally, while not explicitly laid out in the proposed rule, we are concerned that this proposal requires specialized skills that will force participants to contract with third parties to extract the data and submit to CMS, incurring fees for a service they do not currently perform. Because CMS has not published specific data elements, vendors will be forced to develop and implement these changes in a short period of time. EHR upgrades are typically bundled together and pushed out as a package, which means that if the vendor does not currently have the required data elements included in a current bundle upgrade, it may be a year or more before this is operational at the practice level. At the same time, participants will be unable to financially plan for the likely significant charges to upgrade current systems, or to plan for new systems, putting them at significant financial risk. **We therefore urge the Agency to delay implementation of this requirement until vendors have sufficient time to implement and upgrade current systems.**

Furthermore, ASTRO would like clarification regarding the applicability of the Office of the National Coordinator (ONC) for Health Information Technology's 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule, which permits vendors to charge fees for: developing, deploying, and upgrading application programming interface (API) technology, and recovering costs of supporting API usage for purposes other than patient access, exchange, and use.

We are aware that vendors are required to upgrade their products to remain compliant with federal regulations, requiring significant investment in the products. However, these costs are often passed on directly to physicians. **As we have mentioned previously in other comment letters, we are concerned that vendors will use every new, regulatorily-required update or module as an opportunity to generate additional charges and fees for their products. These excess charges are a financial burden for many practices, especially for small and rural practices, which often find these costs prohibitive. If the RO Model is mandatory, CMS has an obligation to offset these costs passed down by vendors.**

Finally, CMS is proposing the use of a template for those practices that are unable to submit these data electronically. **We appreciate CMS' understanding that not all practices can submit electronically and appreciate the proposed availability of a template. However, because neither the data elements nor the template are available, we are unable to sufficiently comment on whether this will be burdensome to practices.** In general, a template will increase staff time, practice overhead costs, and since these data elements may not be discrete fields within the EHR, someone will have to transcribe information out of the medical record for submission in either electronic form, or via a template. **We recommend the Agency delay implementation of this requirement until the data can be submitted electronically by all providers in a useful and meaningful way.**

We appreciate CMS' recognition that standardization will change quality and will make data sets more meaningful to the Agency. In fact, we have developed, and are working to expand, a set of minimum data elements designed to work for just this purpose, as well as for clinical trials and

database collections¹⁷. Initiatives like the American Society of Clinical Oncology's (ASCO) mCODE are also addressing these issues and are specifically looking at some of the same data elements itemized in the proposed rule. Specialty societies are working with their memberships to develop data sets that will provide meaningful data; however, this effort is still in the early stages, with one or two use cases in development. **We recommend that CMS allow time for this development to mature and delay implementation of this requirement. At the same time, we request clarification on the collection mechanism and structure of these data elements.**

Patients over Paperwork

ASTRO appreciates that CMS has been carefully considering and rolling back unnecessary regulatory reporting burdens through its Patient's Over Paperwork initiative. **However, we urge the Agency to carefully consider the burden associated with quality and clinical data collection requirements, particularly given that practices will be spending a significant amount of time and resources shifting their business models to the new alternative payment model.** The more time spent on needless input of measures that do not result in improved patient care is not time well spent. **ASTRO urges the Agency to consider a stepped approach to the implementation of the quality component of the RO Model.** Other models, such as the OCM feature monthly payments to account for resource use associated with these added requirements. No such policy is applied in the RO Model, and while we recognize there is value to the application of some quality measures to ensure patients receive appropriate care, it is difficult to balance that with the significant resources required to submit that data. Again, we note that under a mandatory model, practices have no choice but to assume these costs, and therefore CMS has an obligation to offset these added costs that are solely attributable to the RO Model.

Proposed Calculation for the Aggregate Quality Score (AQS)

The proposed AQS is based on each Professional and Dual participant's performance on the set of proposed evidence-based quality measures compared to those measures' benchmarks; reporting of data for proposed pay-for-reporting quality measures; and reporting of clinical data elements. CMS is proposing to weight 50 percent of AQS on the successful reporting of required clinical data and the other 50 percent of the AQS on quality measure reporting. RO Model participants would receive up to ten points for their performance rates on each measure, similar to MIPS. In cases where Professional participants and Dual participants do not have sufficient cases for a given measure, that measure will be excluded from the AQS denominator calculation and the denominator will be recalibrated to reach a denominator of 50 points to prevent participants from receiving any benefit or penalty for having an insufficient number of cases. **We appreciate the Agency aligning quality programs, and the distinction between pay-for-performance and pay-for-reporting. As discussed above, we welcome further clarification on the proposed benchmarks that the Agency will use for AQS calculations.**

To calculate the AQS, CMS proposes to sum each Professional or Dual participant's points awarded for clinical data reporting with its aggregated points awarded for quality measures to reach a value that would range between 0 and 100 points. The AQS would be calculated

¹⁷ Hayman, James A., et al. "Minimum Data Elements for Radiation Oncology: An ASTRO Consensus Paper," Practical Radiation Oncology. August 2019.

approximately eight months after the end of each performance year and applied to calculate the quality withhold payment amount for the relevant performance year. **ASTRO urges CMS to redefine the timeline for payment, as a delay in payment could cause many participants to experience financial hardships, especially those practices in small and rural communities, or those practices that don't have a large Medicare patient population.**

Additional Proposed Data Shared by RO Participants

In addition to quality measures and clinical data elements data collection described above, CMS is also proposing that RO participants supply certain types of practice specific data. Information includes the RO participants TIN, in the case of freestanding centers and PGPs, or CCN in the case of a HOPD. RO participants will also be asked to confirm their NPIs for the physicians who bill radiation therapy services using the applicable TINs. Additionally, RO participants may be required to report on the number of Medicare and non-Medicare patients treated with radiation therapy during their participation in the model.

Additionally, RO participants will be asked to submit administrative data, including the costs to provide care, such as the cost of a linear accelerator and how frequently the radiation machine is used on an average day; current EHR vendors; and accreditation status.

ASTRO questions the necessity of requiring practices to report on the cost of equipment and frequency of treatment. Neither of these data points have any bearing or relevance to the operationalization of the model and merely reflect additional administrative reporting burden that is of little value. Additionally, there is no standardized methodology for collecting this type of data, which would make any conclusions drawn from it meaningless. ASTRO urges the Agency to refrain from requiring any additional data collection other than confirming NPIs, TINs and CCNs that are participating in the model.

Certified Electronic Health Records Technology (CEHRT)

In order to be an Advanced APM, the RO Model must meet the criteria specified in the MACRA of 2015, which requires participants to use CEHRT. For performance periods beginning in 2020, to meet this requirement, an Advanced APM must require at least 75 percent of eligible clinicians in the APM entity to use CEHRT to document and communicate clinical care to their patients or other health care providers. RO Model Professional and Dual participants will be required to certify their intent to use CEHRT throughout the model year within 30 days of the start of the first performance year. **ASTRO requests clarification on which edition CEHRT the Agency is requiring and recommends that it align with other quality reporting programs. Additionally, it is unclear why participants must certify their intent to use CEHRT at the beginning of the performance year, and not at the end.**

Patient Safety Organizations

The Agency is proposing that each Technical and Dual participant annually attest to active participation in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). **ASTRO is pleased that the Agency recognizes the importance of reporting and learning from patient safety data to AHRQ-listed PSOs. However, we request the following change (in red) to the language found in the proposed rule:**

At such times and in the form and manner specified by CMS, each Technical participant and Dual participant must annually attest to whether it actively participates in an ~~radiation oncology-specific~~ AHRQ-listed patient safety organization (PSO) ~~that collects and reports on radiation oncology safety data~~ (per their PSO Provider Service Agreement).

The [RO-ILS: Radiation Oncology Incident Learning System®](#) (RO-ILS) is a part of Clarity PSO, an AHRQ-listed PSO, and is the only medical specialty society-sponsored radiation oncology incident learning system. We want to make sure that those RO Model participants who are also RO-ILS participants are able to leverage this participation to comply with the PSO requirement. The mission of RO-ILS is to facilitate safer and higher quality care in radiation oncology by providing a mechanism for shared learning in a secure and non-punitive environment. With over 500 facilities enrolled in the program and more than 10,000 events reported to the PSO, RO-ILS has released numerous aggregate reports and published findings in *Practical Radiation Oncology*, a peer-review journal to increase awareness of error-prone processes and possible mitigation strategies, including information about human factors engineering.

In addition, ASTRO recommends that the PSO participation requirement not go into effect until the second performance year as it is unlikely that all RO Model participants are currently participating in a PSO that collects radiation oncology-specific data, like RO-ILS. It is important to note that before a practice can participate in a PSO, it must first sign a contract with the PSO to establish the federal protections outlined in the Patient Safety and Quality Improvement Act of 2015 (PSQIA). On average, it takes a RO-ILS participant up to 6 months to contract with the PSO and additional time to receive training and implement the program locally before any data is submitted.

Monitoring for Compliance

In order to monitor for compliance, the Agency is also proposing that all Professional participants and Dual participants document in the medical record that they have complied with seven monitoring requirements.

As mentioned previously, EHR vendors may need to develop discrete fields for these elements as they may be typically captured in clinical notes. ASTRO remains concerned with any financial costs that participants may incur when the onus really should be on the vendors. **ASTRO requests clarification on how this data is evidenced and what types of feedback, based on this data, will be provided to participants. We further request clarification on how participants provide evidence of compliance with these requirements if the medical record does not currently collect this data, or if it is found in other systems or clinical notes.**

Our comments on each of the specific monitoring requirements follows:

1. Discussed goals of care with each Medicare beneficiary before initiating treatment and communicated to the beneficiary whether the treatment intent is curative or palliative;

Oncology information systems do not always include intent as a data field. If it is included, it does not indicate communication with the patient. **ASTRO requests clarification on the intent of this requirement.**

2. Adheres 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;

Clinical decision support is not common in radiation oncology software. **ASTRO requests clarification on how this will be assessed and documented.**

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

ASTRO requests clarification as to whether this assumes documentation of these data elements in the medical record. Additionally, we request clarification on whether CMS intends this to be use of the AJCC staging system? How does the Agency envision handling those cancer types that do not have a TNM staging system like brain tumors and leukemias.

4. Assesses the Medicare beneficiaries' performance status as a quantitative measure determined by the physician;

ASTRO requests clarification as to whether a specific scale (i.e., Karnofsky, ECOG) or whether it is more generally the use of a standardized scale?

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

This requirement is inconsistent with the Treatment Summary Communication – Radiation Oncology quality measure already included in the model. The measure specifications specify one month and include referring physician and patient. **ASTRO recommends that CMS align this requirement with the quality measure.**

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

We appreciate that CMS is developing educational materials around this and look forward to being able to provide comments on them.

7. Performs and documents 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 appreciates the phased-in approach to the peer review requirement. However, it is not clear how and where peer review documentation will be recorded, measured or abstracted. Also, is the Agency proposing to place requirements on when peer review takes place? Peer review can occur before treatment planning, before treatment and even retrospectively after treatment. There is significant debate in the field about whether peer review should occur primarily for curative cases or all cases. Additionally, there is discussion about prioritization of early peer review for hypofractionated and SBRT/SRS cases compared to conventionally fractionation cases.

ASTRO is working to develop consensus on these issues and we are concerned that an arbitrary mandate, while well-intentioned, could undermine efficient use of resources.

Additionally, we are concerned about small and rural practices who currently have limited access to other practitioners to perform peer review to the extent required by this proposed rule. **We believe this requirement will add complexity and burden to small and rural practices that may not have the same peer review resources as those in larger practices and will need additional time to implement. We suggest that CMS reduce the required number of patients required for each performance year or provide an exemption to those practices that show good-faith in trying to comply.**

ASTRO recommends a more simplified approach to these monitoring requirements by establishing an accreditation requirement as part of the RO Model. Accreditation standards include each of these components as part of the assessment. ASTRO's 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 ASTRO standards translate the goals outlined in the *Safety is No Accident* framework into objective, verifiable expectations for performance in radiation oncology practice¹⁸.

Facilities that obtain APEx practice accreditation have demonstrated a commitment to quality, safe care and have had their systems, personnel, policies and procedures validated by an external surveyor. It offers transparent, measurable, evidence- and consensus-based standards that emphasize a professional commitment to safety and quality. ASTRO recognizes that not all participating practices are currently APEx accredited, and consideration should be given to accreditation programs with comparable quality measures and patient safety standards. The accreditation requirement serves as an anchor to the key safety issues required for high quality radiation oncology care.

ASTRO urges CMS to consider accreditation in lieu of the monitoring requirement. Recognizing that not all practices are currently accredited and it would take time to gain accreditation, a three-year phase in period could be established to give practices the opportunity to come into compliance with this requirement.

Performance Feedback

CMS proposes to utilize clinical data, quality measures reports, claims data and compliance monitoring to provide information to RO Model participants on their adherence to evidence-based practice guidelines, quality and patient experience measures, and other quality initiatives. The frequency and design of these reports will be determined in conjunction with the RO Model implementation and monitoring contractor. **ASTRO requests clarification and input on the frequency and design of these reports. We believe that in order for such reports to be meaningful and impact change, they must contain patient-specific information, with guidance on potential improvements, and be provided to participants in a timely fashion.**

Local Coverage Determination

¹⁸ *Safety is No Accident: A Framework for Quality Radiation Oncology Care*. American Society for Radiation Oncology. 2012.

CMS asserts that the RO Model's episode payment is designed to give radiation oncologists greater opportunity to clinically manage episodes of care. However, according to the proposed rule, local coverage determinations (LCDs), would still apply to all radiation therapy services provided in an episode.

The application of LCDs is a form of prior authorization. ASTRO has significant concerns with the inappropriate use and proliferation of prior authorization. ASTRO urges CMS to abandon the use of LCDs to determine coverage for those services delivered to Medicare beneficiaries as part of the RO Model. The establishment of episode-based payments, which effectively decouple payment from modality of treatment, no longer warrants the use of LCDs or other methods of prior authorization. If the Agency is truly committed to giving radiation oncologists greater latitude to make care decisions that are in the best interest of their patients, then there is no need for the application of LCDs.

Annual Reconciliation and True Up Process

CMS proposes to establish an annual reconciliation process that would occur in August (August 2021 for the 2020 performance year) following each performance year in order to allow time for claims run-out, data collection, reporting and calculating results that will be used to reconcile payments that are either due to the RO participant or payments owed to CMS that exceed the withhold policies. Then, a subsequent true-up of the reconciliation would take place that would calculate additional payments or repayments for incomplete episodes and duplicate radiation therapy services that are identified after the claims run out period. This true-up process would take place a year after the reconciliation process (August 2022 for the 2020 performance year).

ASTRO is concerned that the 20-month lag between the end of the performance period and the true up period has the potential to put practices in financial jeopardy.

Furthermore, CMS fails to explain its basis for adopting withholds to account for quality measures, patient experience, and incorrect payments in payment to participants. CMS proposes a 2 percent quality withhold to satisfy the quality-based payment requirements of 42 C.F.R. 414.1415(b)(1) and a 1 percent patient experience withhold to account for patient experience in the model, but fails to explain the basis for its determination that a withhold is the only way to include quality and patient experience in payment determinations.¹⁹

Similarly, with regard to the proposed 2 percent incorrect payment withhold, CMS explains that a withhold would “decrease the likelihood of CMS needing to recoup payment, which could cause an administrative burden on CMS and potential disrupt a RO participant’s cash flow.”²⁰ Furthermore and according to the proposed Model, withheld funds that are eventually paid to the participant through the reconciliation process do not allow for collection of coinsurance related to those funds from the Medicare FFS beneficiary or the beneficiary’s supplemental insurance. This limitation further limits cash flow for the participant in this model that practices outside the model and participants in other CMS alternative payment models do not experience. CMS’s justification for its decision to withhold based on the potentially disruptive impact of a recoupment on a RO participant’s cash flow is inconsistent with the annual reconciliation and

¹⁹ 84 Fed. Reg. 34504, 34509.

²⁰ *Id.* at 34509

true up process, as well as its justification for ignoring the potential disruption of a withhold on a RO participant's cash flow.

To the extent that CMS is relying on the financial risk standard for Advanced APMs in 42 C.F.R. 414.1415(C)(1) to justify its proposed withholds, CMS provides no legally sufficient basis for not selecting one of the other two enumerated options for achieving financial risk.²¹ In particular, given the potential impact on cash flow for RO participants, we see no reason why CMS would not adopt a process similar to the MIPS program, which involves identifying any over or under payments associated with incorrect payments and quality measures performance payments and applying them going forward in the model to the episode-based payments of future years. That same 20-month reconciliation and true up period can be used to determine incorrect payments and quality performance in the first performance year and then any associated modifications to payment can be applied beginning in performance year 3.

Timely Error Notice and Reconsideration Request Process

CMS is proposing a timely error notice and reconsideration request period in which RO participants may dispute suspected errors in the calculation of their reconciliation payment amount or repayment amount. The dispute process is limited to the reconciliation process and will not be extended to RO Model pricing methodology or AQS methodology. The Agency is proposing a two-level process for RO participants to request reconsideration of reconciliation determinations. The first level is a timely error notice process and the second level is a reconsideration review process. The timely error notice allows RO participants to notify CMS of reconciliation errors within 30 days from the date the RO reconciliation report is issued. CMS would then respond within 30 days to either confirm the calculation error or to verify that the calculation is correct. In the reconsideration review process, RO participants would be permitted to dispute CMS' response to the RO participant's identification of errors in the timely error notice, by requesting a reconsideration review. The reconsideration review must be submitted within 10 days of the issue date of CMS' written response to the timely error notice. CMS proposes that a CMS reconsideration official will issue a written determination within 60 days after the submission of review materials. **ASTRO urges CMS to extend the 30-day error notification timeline to 45 days which aligns with the existing CMS appeals process.**

RO Model: Advanced APM and MIPS APM

CMS intends for the RO Model to qualify as an Advanced APM and to also meet the criteria to be a MIPS APM. The Agency proposes that the RO participant, specifically either a Professional participant or a Dual participant, would be the APM entity. The Agency projects that 82 percent of RO participants will receive the APM incentive payment for at least one performance period during the model performance period, based on applying the 2019 Quality Payment Program (QPP) final rule qualification criteria to simulated billing and treatment patterns for each QPP

²¹ 42 C.F.R. 414.1415(c)(1) reads: "an APM must, based on whether an APM Entity's actual expenditures for which the APM Entity is responsible under the APM exceed expected expenditures during a specified QP Performance Period, do one or more of the following: (i) Withhold payment for services to the APM Entity or the APM Entity's eligible clinicians; (ii) Reduce payment rates to the APM Entity or the APM Entity's eligible clinicians; or (iii) Require the APM Entity to owe payment(s) to CMS."

performance year during the RO model test.²² As discussed in more detail in the section below on waivers, the APM incentive payment would apply only to the professional episode payment amounts and not the technical episode payment amounts.

In order to be an Advanced APM, an alternative payment model must satisfy three specific criteria 1) Use of Certified Electronic Health Records Technology; 2) Payment Based on MIPS comparable quality measures; and 3) Meet the nominal financial risk standard. Additionally, MACRA sets forth that full capitation arrangements also meet the criteria for Advanced APMs. According to statute, “a full capitation arrangement means a payment arrangement in which a per capita or otherwise predetermined payment is made under the APM for all items and services furnished to a population of beneficiaries during a fixed period of time, and no settlement is performed to reconcile or share losses included or savings earned by the APM entity.” 42 C.F.R. 1415(C)(6).

ASTRO understands the RO Model is a capitated payment arrangement in that it meets each of the criteria as laid out in MACRA and the implementing regulations. Thus, there should be no APM entity that does not qualify as an Advanced APM participant. CMS should therefore revise its 82 percent projection, given that all of the criteria for Advanced APMs are necessarily met through the other aspects of the RO Model as proposed. To the extent the projection means that 18 percent of RO participants are expected to fail to meet the requirements for an Advanced APM, there is a clear flaw in the proposed model that must be addressed.

Medicare Program Waivers

CMS is proposing to waive the MACRA-required Technical Component Payments in the calculation of the APM incentive payment. According to MACRA, Qualified Advanced APM Participants are eligible to receive 5 percent of his or her prior year estimated aggregate payments for covered professional services. CMS believes it is necessary to exclude payments for the technical RO Model-specific HCPCS codes from the estimated aggregate payment amounts for covered professional services used to calculate the APM incentive payment because those services are considered “technical” in nature and represent the cost of the equipment, supplies and personnel used to perform the procedure.

CMS asserts that if the waiver were not applied and technical RO Model-specific HCPCS codes are included in the calculation, then radiation oncologists delivering radiation therapy services in the freestanding setting would have technical radiation therapy services included in the calculation of the APM incentive payment, but radiation oncologists delivering radiation therapy services in hospital outpatient settings would not have those services included in the calculation of the APM incentive payment. CMS believes this scenario would result in Dual participants changing their billing behavior by shifting their site of service from the hospital setting to the freestanding setting, thus jeopardizing the site neutral intent of the model.

ASTRO believes that the proposal to exclude the technical component from the APM incentive payment is particularly egregious given the proposed 5 percent discount on technical component payments. The technical component for radiation therapy services includes the fixed costs associated with practice expenses for the equipment and personnel

²² 84 Fed. Reg. 34569.

involved in the delivery of radiation therapy services. Radiation oncology clinics are an example of a practice type in which the ratio of fixed costs far exceeds variable costs. The total capital required to open a freestanding radiation oncology center is approximately \$5.5 million, plus an additional \$2 million in annual operating and personnel expenses. These significant fixed investments far outweigh the variable costs of operating a radiation oncology clinic and should be given consideration as part of any alternative payment model. While it is important to reduce the cost of care and drive value in healthcare, it is also important to ensure that efforts to generate savings do not cause financial hardship and access to care issues for those specialties with high fixed costs and the patients they treat. This is particularly important for practices operating in rural areas.

ASTRO notes that the site of service differential that CMS seeks to avoid in pursuing this proposed waiver—that the APM incentive payment for radiation oncologists delivering radiation therapy services in the freestanding setting would include technical radiation therapy services while the payment for radiation oncologists delivering radiation therapy services in hospital outpatient settings would not—would occur because it is built into the payment methodologies of the OPPS and PFS. In light of the fact that this payment differential already exists outside of the RO Model, ASTRO sees no legal or policy reason as to why the RO Model should override the payment methodologies underlying the PFS and OPPS by excluding the technical component payment from the APM incentive payment. Furthermore, there is no legal or policy basis for CMS’ conclusion that the site neutral intent of the model is served by eliminating a payment that radiation oncologists at freestanding clinics would otherwise be entitled to receive.

CMS fails to provide a justification for its decision to eliminate the APM incentive payment that meets the APA’s legal threshold for regulatory actions. Where the statute establishes a payment to incentivize participation in Advanced APMs²³ and CMS has interpreted that payment to be contingent on participation alone,²⁴ CMS proposes to mandate participation *and* to waive its obligation to pay for such participation. When put together these arbitrary actions bring radiation therapy providers into a new payment model that fails to compensate them for their participation. This regulatory action conflicts with the spirit and letter of MACRA and suggests that the incentive waiver is nothing more than a payment cut disguised as a test. **ASTRO recommends removing the waiver for the APM incentive payment and allowing for the 5% bonus payment to be applied to the technical payments of freestanding centers.**

Oncology Care Model (OCM)

Because the OCM and RO Model both involve care for patients with a cancer diagnosis who receive radiation therapy services, CMS anticipates that there will be Medicare beneficiaries who will be in both OCM and RO Model episodes. The OCM is a total cost of care model that encompasses a six-month episode of care. OCM episodes that include radiation therapy services

²³ Section 1833(z) of the Act (added by section 101(e)(2) of the MACRA).

²⁴ CMS, Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models, 81 FR 77008, 77400 (Nov. 4, 2016) (CMS has expressed that “the structure of the law is clear in that the APM Incentive Payments are earned through participation in APMs that are designed to be challenging and involve rigorous care improvement activities.”)

receive a risk adjustment when calculating episode benchmarks, with the goal of mitigating incentives to shift these services outside the episode.

CMS proposes that for those instances in which radiation therapy services are provided before or after the OCM episode, then the radiation therapy services that are part of that RO Model episode would not be included in the OCM episode. If the entire RO Model episode occurs completely within the six-month OCM episode, then the associated radiation oncology payments for radiation therapy services would be included in the OCM episode. CMS will add the RO Model's discount and withhold amounts to the total cost of the OCM episode during the OCM's reconciliation process to ensure there is no double counting of savings and no double payment of the withhold amounts. This provides both the medical oncologist and the radiation oncologist with the opportunity to collaboratively work within a value-based payment arrangement, while allowing them to independently manage the delivery of those services for which they are accountable.

In those cases where the two models partially overlap, CMS proposes to allocate the RO Model payments for radiation therapy services and the RO Model discount and withhold amounts to the OCM episode on a prorated basis, based on the number of days of overlap.

ASTRO appreciates that CMS has recognized the RO Model and the related services provided as a distinct and separate process of care. We appreciate that there will be instances in which the model fits neatly within an OCM episode of care and instances in which it overlaps with the OCM episode of care. ASTRO would appreciate further clarification regarding how they pro-rated payments will be determined and how they prorated payments will be distributed to providers.

Conclusion

In general, ASTRO is pleased that a RO Model is moving forward, as the Society agrees with CMS that there is great promise for an alternative payment model to drive even higher quality care in radiation oncology. Since the passage of MACRA, ASTRO has urged CMS to create an Advanced APM for radiation oncology, and the release of the RO model is a significant step in that direction, despite the concerning aspects of the proposal.

ASTRO certainly recognizes many of our model recommendations in the CMS RO Model, confirming that the agency carefully considered and built upon the model ASTRO proposed. Several components of the model will help address our longstanding concerns about payment stability, and we generally agree with the inclusion of meaningful quality measures and programs.

In closing, ASTRO thanks the Agency for the opportunity to engage on the development of this proposed alternative payment model for radiation oncology. While we believe that there are flaws in this initial design, we do not believe any of them to be insurmountable and look forward to the opportunity to refine this proposal so that it can be successfully implemented. If you have any questions regarding the recommended revisions found in our comments, please contact Anne Hubbard, Director of Health Policy at 703-839-7394 or Anne.Hubbard@ASTRO.org.

Sincerely,

ASTRO Comment Letter on RO Model Proposed Rule
September 16, 2019
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Laura I. Thevenot
Chief Executive Officer

APPENDIX A

Common Clinical Scenarios involving Multiple Physicians and Sites of Service

- 1. *Physician in freestanding facility does the EBRT and then the same physician does the brachy in the freestanding center***
 - a. Physician would be a Dual Participant. Seemingly no issues in the RO Model here.
- 2. *Physician in freestanding facility does the EBRT and then same physician does the brachy in the HOPD setting***
 - a. Physician would be a Dual Participant due to the EBRT, and hospital would be a second Technical Participant.
 - b. In the current proposal, the hospital would not get a technical payment. This is problematic for the freestanding physicians in this case and would require some mechanism for reconciliation with the hospital for technical costs of operating room time. **ASTRO recommends that a FFS payment be made for the TC associated with the brachytherapy delivered in the HOPD setting.**
- 3. *Physician in freestanding facility does the EBRT and then a different physician does the brachy in the HOPD setting***
 - a. If the brachytherapy physician is in a different TIN, then would the brachytherapy be paid FFS?
 - b. If the brachytherapy physician is a different physician than the one who did the EBRT but is in the same TIN as initial EBRT physician, we would run into the same problem as #2 above. **If so, ASTRO urges the Agency to reimburse the second physician at FFS rate.**
- 4. *Physician in HOPD does the EBRT and same physician then does the brachy in the same HOPD***
 - a. Both the physician and hospital are in the same TIN → Physician would be Professional Participant, Hospital Technical Participant. No issues with this scenario
- 5. *Physician in HOPD does the EBRT and a different physician then does the brachy in the same HOPD***
 - a. If the physician who did the EBRT, the second physician who did the brachy, and hospital are in the same TIN → First physician who did the EBRT would be Professional Participant, Hospital would be the Technical Participant. What would happen to the second physician who delivered the brachy? Since in the same TIN, that second physician would not be a PC component or FFS?
- 6. *Physician in one HOPD or Freestanding center does the EBRT but patient is then sent to a different physician (with a different TIN) who then does the brachy in a different HOPD or Freestanding center***
 - a. Physician who did the EBRT has a different TIN than the physician who did the brachytherapy, and the first HOPD where EBRT was done has a different TIN than

the second HOPD. It is ASTRO's understanding that the first physician who did the EBRT would be the Professional Participant of the episode, the first hospital would be the Technical Participant, or if EBRT was in freestanding center that first physician would be a Dual Participant. The second physician and the second hospital or freestanding center would get paid FFS. **ASTRO seeks CMS' confirmation of this understanding.** Additionally, does this protocol apply if physician and both hospitals are in the same CBSA?

APPENDIX B – Business Rules

Cancer Type	Rules for Identifying Episode as Palliative	Exclude Services from All Episodes
Anal Cancer	Rule 1: <10 Radiation Treatments (77412)	
	Rule 2: SBRT is only modality (77373)	
Bladder Cancer	Rule 1: <10 Radiation Treatments (77412)	
	Rule 2: SBRT is only modality (77373)	
	Rule 3: <10 Radiation Treatments (77402)	
Bone Metastases	N/A	exclude C2616 services
Brain Metastases	N/A	exclude C2616 services
Breast Cancer	Rule 1: SRS is only modality (77371,77372)	
CNS Tumor	N/A	
Cervical Cancer	Rule 1: ≤10 Radiation Treatments (77412)	
Colorectal Cancer	Rule 1: ≤10 Radiation Treatments (77412)	
	Rule 2: SRS is only modality (77371,77372)	
	Rule 3: ≤10 Radiation Treatments (77402)	

Head & Neck Cancer	Rule 1: ≤ 10 Radiation Treatments (77412)	
	Rule 2: SRS is only modality (77371,77372)	
Kidney Cancer	N/A	
Liver Cancer	Rule 1: ≤ 10 Radiation Treatments (77412)	
Lung Cancer	Rule 1: ≤ 10 Radiation Treatments (77412)	
	Rule 2: SRS is only modality (77371,77372)	
Lymphoma	N/A	
Pancreatic Cancer	N/A	
Prostate Cancer	Rule 1: ≤ 10 Radiation Treatments (77386)	
	Rule 2: ≤ 10 Radiation Treatments (77412)	
	Rule 3: ≤ 10 Radiation Treatments (77402)	
Upper GI Cancer	Rule 1: ≤ 10 Radiation Treatments (77412)	
	Rule 2: SBRT is only modality (77373)	
	Rule 3: SRS is only modality (77371,77372)	

Uterine Cancer	Rule 1: ≤ 10 Radiation Treatments (77412)	
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