

September 16, 2019

Seema Verma, Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Attention: CMS-5527-P  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244

Re: Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures;  
CMS-5527-P

Dear Administrator Verma:

The American Association of Physicists in Medicine<sup>1</sup> (AAPM) is pleased to submit comments<sup>1</sup> to the Centers for Medicare and Medicaid Services (CMS) in response to the July 18, 2019 *Federal Register* notice regarding the Radiation Oncology (RO) Model proposed rule. Please note that the AAPM submitted two comment letters regarding this proposed rule. The present letter addresses concerns and recommendations related to the design and implementation of the RO Model.

CMS proposes the creation and testing of a new payment model for radiation oncology. The intent of the proposed RO Model is to promote quality and financial accountability for episodes of care centered on radiation therapy (RT) services. The RO Model would test whether prospective episode-based payments to physician group practices (PGPs), hospital outpatient departments (HOPDs), and freestanding radiation therapy centers for radiation therapy episodes of care would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

Under this proposed RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee for service beneficiaries diagnosed with certain cancer types. The base payment amounts for RT services included in the RO Model would be the same for hospital outpatient departments and freestanding radiation therapy centers.

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<sup>1</sup> The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography CT, MRI, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to insure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various State regulatory agencies. AAPM represents over 7,000 medical physicists.

While we support CMS efforts to establish an alternative payment methodology for radiation oncology that would reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries, **we have grave concerns regarding mandatory participation and the number of practices required to participate, timing of model implementation, inclusion of certain RT services, the payment and pricing methodology, undue administrative and financial burden, and the potential negative impact on Medicare beneficiary access to safe and high-quality cancer care.**

**Reducing payment will not improve quality but 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. With virtually no positive incentives, payment cuts of this magnitude to required RO Participants are unjustified. The currently proposed RO Model does not meet the intent of the MACRA legislation nor move toward value-based payments.**

**The proposed RO Model is complicated and requires changes to coding, claims generation, claims processing, participant-specific modifiers and adjustments, withhold calculations, payment programming, and software updates for electronic health records (EHRs). Operationalizing the RO Model on both the Medicare contractor side and mandatory RO Participant side will be extremely challenging.**

### **Required Participation**

CMS proposes that certain Medicare participating physician group practices (PGPs), hospital outpatient departments (HOPDs) and freestanding radiation therapy centers that furnish RT services (RT providers or RT suppliers) in randomly selected Core-Based Statistical Areas (CBSAs), would be required to participate in the RO Model either as “Professional Participants,” “Technical Participants,” or “Dual Participants.” CMS proposes to sample 40 percent of all eligible RO episodes in eligible CBSAs nationwide. Those CBSAs and zip codes selected for mandatory participation will be announced in the final rule.

When ASTRO developed and submitted their Radiation Oncology Alternative Payment Model to CMS in April 2017 the framework was based on a shared-risk, phased-in voluntary program for radiation oncology providers to participate in an advanced alternative payment model (APM) with the potential to be scaled up over time.

The RO Model as currently proposed is not only mandatory for a significant number of randomly selected providers but is 100 percent risk based with no hardship exemptions and no opportunity for other providers to opt-in to the model. **Mandatory participation of such a large cohort of practices presents a systemic risk to the specialty and its patients should there be difficulties with implementation. There is a significant risk of potential unintended consequences associated with more than one-third of radiation oncology providers generating all of the savings associated with this proposed RO Model given that the model has never been tested.** As proposed, the RO Model has the potential to create competitive disadvantages for those required to

participate, could impose financial hardships on capital expenditure intensive practices, and impede investing in new technology or purchasing/upgrading medical equipment.

An opt-in provision should be added to the RO Model. This would streamline operations for providers with multiple practices across geographic areas that require mandatory participation and those that are not in randomly selected geographic areas.

**The AAPM recommends that CMS modify participation on a voluntary-basis for the first two of five performance years while the RO Model is tested and refined. CMS could then phase-in mandatory participation over an additional three-year period. Under a mandatory model, the AAPM recommends that CMS scale back the sample size to 10 percent of all eligible RO episodes of eligible CBSAs nationwide.**

**If CMS proceeds with a mandatory RO Model beginning in performance year one, the AAPM recommends that CMS include hardship exemptions for mandatory RO Participants and an opt-in policy for other providers in a geographic area not selected for mandatory participation.**

### **Included & Excluded RT Services**

#### 1. Brachytherapy Sources

We are concerned there may be a misunderstanding as to the nature of “brachytherapy radioactive sources,” which are patient-specific medical devices, not services as the proposed rule indicates.

CMS is proposing to include brachytherapy radioactive elements (i.e. sources) as bundled services in the RO Model. CMS states that they considered omitting these services from the episode payment. After considering either including or excluding brachytherapy radioelements from the RO Model, CMS is proposing to include brachytherapy radioactive elements, rather than omit these services, from the episodes because they are generally furnished in HOPDs and the hospitals are usually the purchasers of the brachytherapy radioactive elements. When not furnished in HOPDs, these services are furnished in ASCs, which CMS is proposing to exclude from the RO Model.

As defined by the FDA, “a radionuclide brachytherapy source is a device that consists of a radionuclide which may be enclosed in a sealed container made of gold, titanium, stainless steel, or platinum and intended for medical purposes to be placed onto a body surface or into a body cavity or tissue as a source of nuclear radiation for therapy.” Brachytherapy sources are medical devices used in therapeutic brachytherapy treatment delivery. The brachytherapy source itself is not a procedure or service but a medical device.

CMS does not include any other medical devices as part of the proposed RO Model. For example, fiducial markers, rectal spacers, brachytherapy needles and catheters are excluded from bundled payment and are paid separately under Medicare fee for service (FFS). In addition, CMS excludes drugs and radiopharmaceuticals furnished in RT services from bundled payment under the proposed RO Model.

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.

Further, all brachytherapy sources are currently paid separately under the Medicare Physician Fee Schedule (MPFS), Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center (ASC) Payment System, with one exception. The High Dose Rate (HDR) Iridium-192 renewable source is not paid separately under the MPFS but is included pro rata in the payment for HDR brachytherapy treatment delivery codes.

In addition, the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA), which was passed by Congress and signed into law December 8, 2003 mandates separate payment of brachytherapy sources provided in a hospital outpatient department effective January 1, 2004.

Specifically, section (b) SPECIAL PAYMENT FOR BRACHYTHERAPY.— (2) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2)) is amended— (A) in subparagraph (F), by striking “and” at the end; (B) in subparagraph (G), by striking the period at the end and inserting “; and”; and (C) by adding at the end the following new subparagraph: “(H) with respect to devices of brachytherapy consisting of a seed or seeds (or radioactive source), the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.”

Therefore, based on the variability of source types and number required for each patient’s cancer, current Medicare payment policy of separate payment for brachytherapy sources furnished in all outpatient sites of services, the MMA 2003 legislative mandate that brachytherapy sources be paid separately in the hospital outpatient setting and CMS’ current proposal to exclude all other medical devices, drugs, radiopharmaceuticals and supplies from the RO Model, brachytherapy sources should also be excluded from bundled payment under the proposed RO Model.

**The AAPM recommends that CMS exclude brachytherapy radioactive elements (i.e., HCPCS A9527, C1715, C1716, C1717, C1719, C1728, C2616, C2634, C2635, C2636, C2638, C2639, C2640, C2641, C2642, C2643, C2644, C2645, C2698, C2699 and Q3001) as RT services under the RO Model.** Brachytherapy radioactive elements would continue to be paid separately under current Medicare FFS payment policy in all outpatient sites of service.

## 2. Surgical Procedures Required for Brachytherapy Treatment Delivery

CMS proposes to exclude low volume RT services from the RO Model. These include certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. CMS is excluding these services from the RO Model because they are not offered in sufficient amounts for purposes of evaluation.

With regard to the “exclusion of certain brachytherapy surgical procedures” noted above, CMS has included 4 surgical catheter/applicator insertion procedures required to provide brachytherapy treatment delivery in the bundled payment (see below). These are surgical services that are outside the scope of radiation oncology services (i.e., CPT codes 77XXX). While the surgical procedures proposed for inclusion may be provided by a radiation oncologist, they are also provided by gynecological oncologists, urologists, obstetricians/gynecologists and even diagnostic radiologists.

- CPT 55920 Placement of pelvic needles/catheters
- CPT 57155 Placement of tandem and ovoids
- CPT 57156 Placement of vaginal cylinder
- CPT 58346 Placement of Heyman capsules

With the exception of CPT 57156 Placement of vaginal cylinder, these are all very low volume services. In addition, CMS chose to include only a select set of surgical codes to be included in the RO Model payment bundle yet excluded other surgical catheter/applicator procedures that are required to provide brachytherapy treatment delivery including, surgical codes 19296, 19298, 20555, 41019, 55874 and 55875. We feel that including any surgical procedures that are related to RT services is setting a bad precedent.

Further, the currently proposed start of episode trigger of the initial treatment planning service (CPT 77261-77263) would mean that gynecological oncologists, urologists, obstetricians/gynecologists and diagnostic radiologists that furnish these surgical procedures would not receive payment for their professional component (PC) services, as the PC National Base Rate would be provided to the radiation oncology provider that furnishes the initial treatment planning service.

**The AAPM recommends that CMS exclude surgical procedure codes 55920, 57155, 57156 and 58346 from the RO Model as they are not provided exclusively by radiation oncologists.**

## 3. Proton Beam Therapy

CMS notes that Medicare payment for RT services has increased substantially. From 2010 to 2016, spending and volume for proton beam therapy in Medicare FFS grew rapidly, driven by a sharp increase in the number of proton beam centers and Medicare’s relatively broad coverage of this treatment.

Proton beam therapy is an effective, evidence-based treatment for some clinical indications. Clinical evidence on proton beam therapy has demonstrated a decrease in complications, higher disease control, improved overall survival rates, and lower risk of secondary cancer for certain cancer

sites. Despite the substantial benefit proton beam therapy holds for some patients, the technology is not widely accessible across the country. Further, important research is ongoing to determine the role of proton beam therapy in additional clinical indications.

While we agree that proton beam therapy utilization may not be appropriate for all patients, protons have shown promise for the treatment of pediatric cancers, head and neck cancers, central nervous system (CNS) cancers and hepatocellular cancer, to name a few. Reimbursement for those cancer sites will be similarly disadvantaged by the proposed RO Model payments relative to IMRT. We are concerned that continued investigation of proton beam therapy will no longer be economically sustainable under the proposed RO Model, limiting the ability of providers to demonstrate improved outcomes for additional indications.

CMS is considering excluding proton beam therapy from the included modalities in the RO model in instances where a RO beneficiary is participating in a federally-funded, multi-institutional, randomized controlled clinical trial for proton beam therapy so that further clinical evidence assessing its health benefit comparable to other modalities can be gathered.

The proposed exclusion criteria is too restrictive. Many proton centers are participating in non-federally-funded multi-institutional registries and clinical trials with the purpose of advancing the treatment modality and demonstrating clinical efficacy. The types of multi-institutional, randomized, prospective, controlled clinical trials that receive federal funding can be extremely challenging and are not always feasible in the field of radiation oncology. Thus, while a considerable portion of the clinical evidence supporting the benefit of proton beam therapy has come from federally-funded trials, data based on non-federally-funded prospective clinical trials, retrospective analyses, and registry data have also been proven to be effective in generating clinical evidence.

Clinical evidence derived from non-federally-funded clinical trials, multi-institutional studies, or clinical registries may provide comparative-effectiveness data to compare health benefits of proton beam therapy versus other RT modalities. The CMS proposal to exclude only federally-funded, multi-institutional, randomized clinical trials is too narrow in scope and will limit important research opportunities that would benefit Medicare beneficiaries and advance the clinical evidence base.

We urge CMS to expand the RO beneficiary exclusion to include all clinical trials (not just federally funded randomized controlled trials) and data registries for continued evidence development. CMS should expand upon its exclusion proposal by using the Medicare evidence development precedent (i.e., both registries structured in compliance with AHRQ guidance and clinical trials registered on [clinicaltrials.gov](http://clinicaltrials.gov)) to continue to advance clinical evidence development.

**The AAPM recommends that CMS exclude proton beam therapy from the RO Model whenever a RO beneficiary is participating in any clinical trial registered on [clinicaltrials.gov](http://clinicaltrials.gov) or data registries structured in compliance with AHRQ guidance.**

## **Radiation Therapy Multi-Modality or Combination Therapy**

There are flaws in the development of the proposed National Base Rates that would result in a significant payment penalty for RO Participants. The AAPM is concerned that the proposed pricing methodology fails to account for a range of complex scenarios and treatment costs for many practices, including RT multi-modality or combination therapy.

Standard of care multi-modality courses of treatment often employ both external beam radiation therapy (i.e., 3D or IMRT) plus a brachytherapy boost. Combination therapy is common in the treatment of cervical cancer, uterine cancer and advanced prostate cancer. Patients who receive combination therapy experience high quality outcomes, including lower morbidity and mortality rates.

Not all radiation oncologists perform brachytherapy procedures and therefore many of these cases will likely involve two physicians, one physician providing EBRT and a different physician providing brachytherapy. Both RT modalities include an initial treatment plan and other planning and preparation services. The current proposed payment methodology will provide inadequate reimbursement for these combination therapies and will continue to undervalue certain services, such as brachytherapy.

Multi-modality or combination therapy for cervical, uterine or advanced prostate cancer should be subject to an alternative payment methodology that reimburses for planning and preparation for two separate RT services provided during the same episode of care. Regardless if the combination therapy is provided by one or two physicians, CMS should provide adequate and fair reimbursement by providing a PC and TC payment for EBRT and a second PC and TC payment for Brachytherapy. Alternatively, CMS should consider paying for the second RT modality (often the brachytherapy boost) under Medicare FFS, regardless if both modalities are furnished by the same physician.

**The AAPM recommends that CMS provide an alternative payment methodology for multi-modality RT services (i.e., combination therapy) provided during a 90-day episode of care. We recommend that CMS establish separate payment episodes for each RT modality, furnished by either one or two providers, involved in the delivery of care for the treatment of cervical, uterine and advanced prostate cancers, identified by ICD-10 codes C53, C54, C55 and C61 respectively. We suggest that CMS create a modifier that identifies that the patient is undergoing multi-modality radiation therapy (i.e., EBRT + Brachytherapy) that triggers two Professional Component and two Technical Component National Base Rates. Alternatively, CMS should consider paying for the second RT modality (often the brachytherapy boost) under Medicare FFS, regardless if both RT modalities are furnished by the same physician.**

## **New Technology and Innovation**

Advances in technology 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. Innovation in radiation oncology has contributed greatly to increased cure rates and reduced side effects from treatment. As currently proposed, the RO Model does not adequately account for the

next generation of advances in the delivery of radiation oncology. CMS must ensure that practices within the RO Model can invest in new technology that provides clinical benefit to patients.

Future innovation may be deterred unless CMS provides a “carve out” for new technologies. Other CMMI models recognize and make allowance for new and advanced drugs and CMS should do the same for medical devices.

**The AAPM recommends that CMS pay fee for service (FFS) rates for any new technology identified by a new CPT code or new technology code during the term of the RO Model. This will ensure the continued growth and adoption of new innovations that improve patient care.**

### **Low Volume Efficacious Radiation Therapy Services**

Calculation of the proposed National Base Rates will lead to inadequate payments for low volume efficacious technologies. For example, Yttrium-90 microspheres (i.e. HCPCS C2616 or Q3001) are used to deliver targeted internal radiation therapy directly to liver tumors via the hepatic artery. This represents a recently available therapy that has shown encouraging results in the treatment of patients with liver cancer. The proposed 2020 Medicare hospital outpatient payment for the Yttrium-90 brachytherapy source alone is \$17,595, while the proposed TC National Base Rate for liver cancer is only \$14,650, which would not cover the cost of the brachytherapy source let alone the procedures related to insertion of the source.

Clinically efficacious technologies like Yttrium-90 targeted internal radiation therapy are low-volume and calculation of the proposed TC National Base Rate for liver cancer would by virtue of the proposed pricing methodology lump low volume technologies with a much higher volume of less expensive conventional RT therapies.

**The AAPM requests that CMS establish a low volume threshold, below which RT modalities are excluded from the RO Model. The low volume threshold would be used to identify and exclude low volume services (e.g., neutron beam therapy, hyperthermia treatment) and would therefore apply to important low volume efficacious technologies.**

**As it relates specifically to Yttrium-90 targeted internal radiation therapy, the AAPM recommends that CMS exclude brachytherapy radioactive elements, including C2616 and Q3001, as bundled RT services under the RO Model.**

### **Pricing Methodology**

CMS proposes to set a separate payment amount for the Professional Component (PC) and the Technical Component (TC) of each of the cancer types included in the RO Model. CMS proposes to determine the episode payment amount for each component (PC and TC) and cancer type using a National Base Rate, with adjustments for a trend factor and the case mix, historical experience, and



geographic location of each model participant (i.e., a physician group practice, HOPD, or freestanding radiation therapy center). The payment amount would also be adjusted for withholds for incomplete episodes, quality, and starting in performance year 3 beneficiary experience.

## 1. Developing National Base Rates

CMS proposes to create a set of National Base Rates for the PC and TC of the included cancer types, yielding 34 different rates. Each of the National Base Rates represents the historical average cost for an episode of care for each of the included cancer types. The calculation of these rates would be based on Medicare FFS claims paid during CY 2015-2017 that are included under an episode where the initial treatment planning service occurred during 2015-2017. From those episodes, CMS would then calculate the amount CMS paid on average to providers for the PC and TC for each of the included cancer types in the HOPD setting, creating the Model's National Base Rates.

When calculating the proposed National Base Rates, CMS utilized only HOPD claims data. CMS states that HOPPS payments have been more stable over time and have a stronger empirical foundation than those under the MPFS. CMS also states that the HOPPS coding and payments for radiation oncology have varied less year over year than those in the MPFS for the applicable time period. CMS adds that, generally speaking, the HOPPS payment amounts are derived from information from hospital cost reports, which are based on a stronger empirical foundation than the MPFS payment amounts for services involving capital equipment.

AAPM supports the proposal of a site neutral payment and appreciates the Agency's commitment to providing RO Participants with stable rates. However, we are concerned with the CMS decision to establish the site neutral test based on HOPD claims data alone. Approximately one-third of cancer care is provided in a freestanding radiation therapy center and the cost of this cancer care is not accounted for in the proposed National Base Rates. We believe that more accurate National Base Rates can be achieved through a blend of MPFS and HOPPS rates, especially for the Professional Component.

In addition, data analysis indicates that the proposed National Base Rates inappropriately includes "incomplete" episodes of care and palliative care, which distorts the true cost of cancer care. The AAPM supports ASTRO's recommendation to adopt business rules to remove these costs that will ensure more accurate National Base Rates.

**The AAPM recommends that the Professional Component National Base Rates be modified to include a blend of the Medicare Physician Fee Schedule (MPFS) and Hospital Outpatient Prospective Payment System (HOPPS) data. In addition, we recommend that CMS remove data for incomplete episodes of care and palliative care from the PC National Base Rates in order to provide more accurate payments.**

While we agree with the use of HOPPS rates to establish the TC National Base Rates, we reiterate our concerns regarding the Comprehensive APC (C-APC) payment methodology. The C-APC methodology does not account for the complexity of cancer care and fails to capture appropriately coded claims, which yields inaccurate payment rates. The C-APC payment methodology provides

inadequate reimbursement and continues to undervalue certain services, such as brachytherapy. CMS should actively monitor how the HOPPS payment methodology impacts the TC National Base Rates.

**The AAPM supports the current CMS proposal that the Technical Component National Base Rates should be based on the HOPD data only. However, we recommend that CMS remove data for incomplete episodes of care and palliative care from the TC National Base Rates in order to provide more accurate payments.**

## 2. Discount Factors, Adjustments and Withholds

### *Discount Factors:*

CMS proposes a discount factor of 4 percent for the Professional Component (PC) and 5 percent for the Technical Component (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.

CMS also withholds PC and TC payments for incomplete episodes (2%), PC quality withhold (2%) and TC patient satisfaction withhold (1% beginning in performance year 3)

The discount factors represent a significant and excessive payment reduction, which risks patient access by causing significant financial issues for such a capital expenditure intensive specialty. Additionally, combined with the withholds, reduced payments have the potential to put many practices at financial risk.

**The AAPM recommends that CMS 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.**

### *Adjustments:*

CMS also proposes additional adjustments based on RO Participant historical-experience and case mix.

Specifically, CMS proposes to use a historical-experience adjustment in which provider participants that are historically inefficient (their actual benchmark total payment is higher than the predicted FFS total payment based on their historical case mix) would receive higher episode payments, while participants whose historical experience is efficient (their actual benchmark total payment is lower than the predicted FFS total payment based on their historical case mix) would receive lower episode payments. Rewarding inefficient providers and penalizing efficient providers would undermine the RO Model's intent, which CMS says is to reduce "program spending through enhanced financial accountability for model participants." Therefore, **CMS should not adopt the historical-experience adjustment. Including a case-mix adjustment should be sufficient to adjust the episode**

**payment for factors beyond a provider's control.** This proposed payment adjustment could disproportionately harm "efficient" practices and result in excessive cuts.

**The AAPM recommends that CMS eliminate the historical-adjustment, which includes an efficiency factor.**

The AAPM is concerned that the amount of discount factors, when combined with additional payment adjustments and other payment withholds, represent an additional reduction to already inadequate payment rates for many RT services. Further, the currently proposed payment methodology could create cash-flow challenges for practices, particularly relative to those not participating in the RO Model. We are very concerned that while CMS is realizing savings from the PC and TC discounts there is no opportunity for RO Participants to earn the money back like under the Oncology Care Model.

### **Monitoring and Compliance**

CMS states that RO Participants would be required to cooperate with the model monitoring and evaluation activities, comply with the government's right to audit, inspect, investigate, and evaluate any documents or other evidence regarding implementation of the RO Model, and to retain and provide the government with access to records. Additionally, CMS would conduct model monitoring activities with respect to the RO Model. CMS believes that the general provisions relating to monitoring and compliance are appropriate for the RO Model, because they must closely monitor the implementation and outcomes of the RO Model throughout its duration.

The proposed RO Model is overly complicated and presents a burden to providers. According to the CMS.gov website, "At CMS, our top priority is putting patients first. CMS Administrator Seema Verma launched the "Patients over Paperwork" initiative, which is in accord with President Trump's Executive Order that directs federal agencies to "cut the red tape" to reduce burdensome regulations. Through "Patients over Paperwork," CMS established an internal process to evaluate and streamline regulations with a goal to reduce unnecessary burden, to increase efficiencies, and to improve the beneficiary experience. In carrying out this internal process, CMS is moving the needle and removing regulatory obstacles that get in the way of providers spending time with patients." The proposed RO Model would undermine the "Patients over Paperwork" initiative by heaping additional administrative tasks and costly requirements on already burdened radiation oncology practices. **CMS should rely heavily on recommendations from the radiation oncology community to ensure that only information that is most meaningful and least burdensome is collected.**

CMS proposes to monitor participants for compliance with many metrics that are historically understood as standards of practice accreditation. **The AAPM recommends that CMS require accreditation of all RO Model Participants as part of model compliance** (please refer to our August 16, 2019 comment letter for additional detail). **The accreditation requirement should be accompanied by a reduction or elimination of CMS' proposed monitoring requirements.**

The abstracting/reporting of quality/safety metrics, clinical data elements, and the monitoring requirements should not be unfunded mandates. CMS needs to include a mechanism to pay practices for doing the reporting and creating the operational infrastructure required to do so.

**The AAPM believes that providers should be paid for data collection outside of the RO Model payment methodology and we request that CMS implement pay-for-reporting for specific clinical data elements.**

### Monitoring Activities

Under this proposal, RO Participants would be required to submit encounter data (i.e., no-pay) claims that include all RT services identified on the RO Model Bundled HCPCS list as services are furnished and would otherwise be billed under the Medicare FFS systems. CMS states that they will monitor trends in utilization of RT services during the RO Model. These claims will not be paid because the bundled payments cover RT services provided during the episode. CMS notes that the encounter data would be used for evaluation and model monitoring, specifically trending utilization of RT services, and other CMS research.

CMS provides no detail regarding the submission of encounter data. We realize this is an operational issue and assume this will be addressed after publication of the final rule. **We have concerns regarding administrative burdens with provider requirements to track all RT services as they are furnished.**

#### 1. Clinical Data Elements

In addition to collecting quality measure data, CMS proposes to collect clinical information on certain RO beneficiaries included in the model from Professional Participants and Dual Participants that furnish the PC of an episode for use in the RO Model's pay-for-reporting approach and for monitoring and compliance.

On a pay-for-reporting basis, CMS would require Professional Participants and Dual Participants to report basic clinical information not available in claims or captured in the proposed quality measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information, on RO beneficiaries treated for five types of cancer under the Model: (1) prostate, (2) breast, (3) lung, (4) bone metastases, and (5) brain metastases. CMS would determine the specific data elements and reporting standards prior to the start of the RO Model and would communicate them on the RO Model website. **We have concerns regarding administrative burden associated with additional pay-for-reporting requirements related to clinical information on 5 specific cancer types. As recommended above, these pay-for-reporting services should be paid separately outside of the RO Model payment methodology.**

#### 2. Data Submitted by RO Participants

In addition to the quality measures and clinical data, CMS proposes that RO participants supply and/or confirm a limited amount of summary information to CMS. This information includes the RO

participant's Tax Identification Number (TIN) in the case of a freestanding radiation therapy center and PGP, or CMS Certification Number (CCN) in the case of a HOPD. CMS would require RO participants to supply and/or confirm the National Provider Identifiers (NPIs) for the physicians who bill for RT services using the applicable TINs. RO participants may be required to provide information on the number of Medicare and non-Medicare patients treated with radiation during their participation in the Model. CMS proposes to require RO participants' submission of additional administrative data upon a request from CMS, such as the RO participant's costs to provide care (such as the acquisition cost of a linear accelerator) and how frequently the radiation machine is used on an average day; current EHR vendor(s); and accreditation status. CMS proposes to do this through annual web-based surveys. CMS states that the data requested for use under the RO Model will be used to better understand participants' office activities, benchmarks, and track participant compliance. **We have concerns regarding additional administrative reporting burden associated with data that has no bearing or relevance to the operation of the RO Model. In addition, there is no standardized methodology for collecting this type of data. The AAPM urges CMS to refrain from requiring any additional data collection other than confirming NPIs, TINs and CCNs that are participating in the RO Model.**

### **Model Performance Period**

CMS proposes to test the RO Model for 5 performance years. CMS proposes to define "model performance period" to mean January 1, 2020, the date the RO Model begins, through December 31, 2024, the last date during which episodes under the RO Model must be completed. Alternatively, CMS is considering delaying implementation to April 1, 2020 to give RO Participants and CMS additional time to prepare.

The proposed RO Model is complicated and requires changes to coding, claims generation, claims processing, participant-specific modifiers and adjustments, withhold calculations, payment programming and EHR software development, testing and updates. We believe it will take practices several months to prepare for operations under a mandatory RO Model.

Given that required participants of the RO Model will not be identified until publication of the final rule, which will occur on or after November 1<sup>st</sup>, a 60-day notice to implement this complex payment system is unrealistic.

**At a minimum, the AAPM recommends that CMS delay implementation of the RO Model until July 1, 2020. However, given the complexity of the alternative payment model and the undue administrative and financial burden, the AAPM recommends that CMS delay RO Model implementation for one year with a more realistic start date of January 1, 2021.**

### **Professional and Technical Billing and Payment**

CMS proposes to pay for complete episodes of care in two installments: one tied to when the episode begins, and another tied to when the episode ends.

Under the proposed billing policy, a RO Participant that furnishes the PC of the episode must bill one of the new RO Model-specific HCPCS codes and start of episode (SOE) modifier. This would indicate within the claims systems that an episode has started. Upon submission of a claim with a RO Model-specific HCPCS codes and SOE modifier, CMS would pay the first half of the payment. A RO Participant must bill the same RO Model-specific HCPCS code that initiated the episode with a modifier indicating the end of an episode (EOE) after the end of the 90-day episode. This would indicate that the episode has ended. Upon submission of a claim with a RO Model-specific HCPCS codes and EOE modifier CMS would pay the second half of the payment.

Some RT episodes of care are completed in one day (e.g., stereotactic radiosurgery or accelerated partial breast irradiation) or over the course of a few weeks (e.g., treatment for metastatic cancer or breast brachytherapy). Given the proposed payment methodology, according to CMS staff during the August 22<sup>nd</sup> Listening Session, the second and final payment would not occur until after the 90-day episode of care has been completed. Meaning that payment would not occur until after Day 90. We think delayed payment may cause a financial burden to many RT providers. We recommend that CMS provide the second and final payment when the EOE modifier is submitted, which could be on Day 2, Day 12 or any number of days prior to the completion of the 90-day episode of care.

**The AAPM recommends that CMS modify the payment methodology and provide the second and final payment when the end of episode (EOE) modifier is submitted, instead of waiting until the completion of the 90-day episode of care.**

### **Medicare Program Waiver and APM Incentive Payment**

CMS intends for the RO Model to qualify as an Advanced APM and to also meet the criteria to be a MIPS APM. In order to be an Advanced APM, the RO Model must meet the criteria specified in the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015.

CMS recognizes that it is necessary to waive certain requirements for the purposes of carrying out the RO Model. Key among the proposed waivers is a recommendation to waive the MACRA-required Technical Component Payments in the calculation of the APM incentive payment.

Specifically, 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.

**The AAPM believes that the proposal to exclude the Technical Component from the APM incentive payment is egregious given the proposed 5 percent discount on Technical Component payments.**

Under the RO Model proposed rule, the 5 percent Advanced APM incentive payment applies only to professional component (PC) services, despite that technical component (TC) payments are still being subjected to the discount and withhold reductions. This proposed policy does not comply with the MACRA statute definition of “professional covered services.”

There is no legal or policy basis for CMS’ conclusion that the site neutral intent of the RO Model is served by eliminating a payment that radiation oncologists at freestanding radiation therapy centers would otherwise be entitled to receive. These arbitrary actions bring radiation therapy providers into a new payment model that fails to compensate them for their participation. CMS’ waiver of the 5 percent APM incentive payment on freestanding radiation therapy center technical payments undercuts the spirit and letter of the MACRA’s intent of encouraging providers to assume risk and participate in alternative payment models. CMS should either remove this waiver or eliminate the 5 percent technical component discount factor.

**The AAPM recommends that CMS remove the waiver for MACRA-required Technical Component Payments in the calculation of the APM incentive payment and allow for the 5% bonus payment to be applied to the technical payments of freestanding radiation therapy centers.**

### **Patient Safety Organizations**

CMS is proposing that each Technical and Dual Participant annually attest to active participation in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). The AAPM is pleased that CMS recognizes the importance of reporting and learning from patient safety data to AHRQ-listed PSOs. **The AAPM supports the ASTRO recommendation to revise the language found in the proposed rule (see below):**

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 a-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. Both AAPM and ASTRO co-sponsor the Radiation Oncology Incident Learning System (RO-ILS). 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.

**The AAPM 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.

The AAPM recommends significant changes to the proposed RO Model that will incentivize the use of safe, efficient and high-quality radiation therapy services that will drive value and generate savings for the Medicare program. We hope that CMS will carefully consider these critical issues during the development of the Radiation Oncology Model final rule. Should CMS staff have additional questions, please contact Wendy Smith Fuss, MPH at (904) 844-2487.

Sincerely,



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