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CMMI Radiation Oncology Alternative Payment Model "RO Model" Final Rule

Summary

On September 18, 2020, the Centers for Medicare and Medicaid Innovation Center issued a final rule establishing a Radiation Oncology Alternative Payment Model (RO Model), effective January 1, 2021. ASTRO has grave concerns about the success of the RO Model given that CMS accepted very few recommendations that ASTRO provided in response to the July 2019 proposed rule. We are particularly disappointed in the Agency's decision to rapidly implement a mandatory model, which has never been tested, on January 1, 2021, during the midst of a declared public health emergency (PHE). ASTRO is asking CMS and working with Congress to delay model implementation.

The RO Model is designed to test whether prospective 90-day episode-based payments to approximately 950 physician group practices (PGPs), hospital outpatient departments (HOPDs), and freestanding radiation therapy centers will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. Mandatory participation by the participants in the pre-selected Core Based Statistical Areas (CBSAs) represents 30 percent of all eligible episodes. According to a preliminary ASTRO analysis, the model appears to oversample rural radiation oncology practices, as 20 percent of the zip codes selected serve rural populations. The Agency estimates savings of $230M over the Model's five-year implementation period. CMS asserts that the RO Model's episode payment is designed to give radiation oncologists greater predictability in payment and greater opportunity to clinically manage episodes of care, rather than being driven by Fee-For-Service payment incentives.

In addition to ASTRO's concerns regarding the implementation timeline and compulsory participation. ASTRO is very disappointed that the Agency only made minimal modifications to the payment methodology to address our concerns regarding the Model's financial impact, which could result in financial jeopardy rather than stability for some practices. This concern is heightened by the financial impact that COVID-19 has had and will likely continue to have on the finances of radiation oncology practices nationwide.

Below is a more detailed summary of the final rule and its impact on radiation oncology practices. ASTRO will release more information as it comes available.

Savings Target

The final RO Model estimates $230M in savings over a 5-year period to achieve CMS' stated goal of 3 percent in overall savings. In the final rule, CMS reduces the percentage of radiation oncology episodes included in the model from 40 percent to 30 percent. According to the final rule, based on a simulation performed by the Agency, it expects to have approximately 500 physician group practices (PGPs) (of which 275 are freestanding radiation therapy centers) and 450 HOPDs furnishing RT services in simulated select CBSAs. Furthermore, the Agency expects the RO Model to include approximately 348,000 episodes, 309,000 beneficiaries, and $5.3 billion in total episode spending of allowed charges over the Model performance period.

ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR RADIATION ONCOLOGY MODEL						
	Year of Model					
	2021	2022	2023	2024	2025	Total*
Net Impact to Medicare Program Spending	$ (30)	$ (40)	$ (40)	$ (50)	$ (60)	$ (230)
Change to Incurred FFS Spending	$ (30)	$ (30)	$ (40)	$ (40)	$ (50)	$ (190)
Changes to MA Capitation Payments	$ (20)	$ (20)	$ (30)	$ (30)	$ (40)	$ (130)
Part B Premium Revenue Offset	$ 10	$ 10	$ 10	$ 20	$ 20	$ 80
Total APM Incentive Payments	$ -	$ -	$ 10	$ 10	$ -	$ 20
Episode Allowed Charges	$ 990	$ 1,030	$ 1,060	$ 1,100	$ 1,120	$ 5,300
Episode Medicare Payment	$ 770	$ 800	$ 830	$ 860	$ 880	$ 4,130
Total Number of Episodes	67,000	68,000	70,000	71,000	72,000	348,000
Total Number of Beneficiaries	65,000	67,000	68,000	69,000	70,000	309,000
*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.						
*Totals may not sum due to roundingand from beneficiares that have cancer treatment spanning multiple years.						

According to the final rule, CMS anticipates that, on average, the RO Model will reduce Medicare FFS payments to PGPs by 6 percent and Medicare FFS payments to HOPDs 4.7 percent, both of which are slightly more than what was stated in the proposed rule. The Agency asserts that the overall revenue impact for participating RO Model practices will be less than 1 percent, given that the model is only applicable to Medicare FFS beneficiaries and not applicable to those patient populations who receive their health care coverage through private payers or Medicare Advantage plans, which combined are an estimated 50 to 60 percent of total HOPD and PGP revenue for RT services. Furthermore, CMS estimates that the revenue impact would be no greater than 5 percent on total revenues on a small number of practices.

ASTRO is concerned that the payer mix breakdown as described above is a broad generalization. Based on the Participating ZIP Code List provided with the final rule, there are a number of practices that serve disproportionately large numbers of Medicare FFS beneficiaries. These practices may recognize even more significant revenue cuts than those estimated by the Agency. The true revenue impact on RO Model participants is likely to vary significantly based on practice-specific payer mix.

ASTRO expressed concern that, as it was proposed, the Model had virtually no positive incentives. That has not changed in the final rule. ASTRO believes 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 Medicare Access and CHIP Reauthorization Act (MACRA) and the goal of value-based payments. As comparison, CMS also released a new mandatory payment model for kidney disease providers Sept. 18, and despite far greater number of participants and kidney disease representing many times more Medicare spending than radiation oncology per year, CMS estimates only $25 million in savings over 5 years from the kidney model.

Mandatory Participation and Timing

ASTRO has significant concerns regarding the Agency's decision to move forward with a model that requires mandatory participation from so many radiation oncology practices at the outset. Requiring this group of almost 1,000 practices to transition to a new payment model in less than 100 days 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 and many are experiencing undue stress due to the PHE. Additionally, we are remain concerned that the Model has the potential to create competitive disadvantages for those participating in the model and, as currently designed, could impose potential financial hardships on practices given the significant fixed costs unmatched in medicine, due to the severity of the payment reductions and lack of recognition for investments in new equipment and technology. To mandate participation in a Model that could limit access to care during a global pandemic is particularly concerning.

In the final rule, CMS disregarded concerns expressed by ASTRO and the broader radiation oncology community regarding mandatory participation. The Agency asserted that it would face complications in its ability to accurately evaluate the model if it were voluntary or phased-in over time.

Types of RO Participants

In the final rule, CMS established three distinct types of 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. 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.

Beneficiary Populations

In the RO Model final rule, CMS includes all traditional Medicare beneficiaries who receive radiation therapy services for at least one identified cancer type in one of the selected CBSAs, as well as 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.

Professional participants and Dual participants must notify Medicare beneficiaries that they are participating in the RO Model by providing written notice to each beneficiary during the initial treatment planning session. CMS will provide a notification template that can be personalized, which explains that the RO participant is participating in the RO Model, provides basic cost sharing responsibilities, and informs the beneficiary of their right to refuse having his or her data shared with CMS.

ASTRO expressed concern that the proposed rule would require Medicare FFS beneficiaries to 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 Prospective 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. ASTRO urged the Agency to 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 or (b) 20 percent of the bundled payment.

In the final rule, CMS disregarded concerns about the potential financial burden imposed by the model. However, the Agency did recognize concerns regarding the application of the 20 percent beneficiary contribution requirement associated with incomplete episodes. Incomplete episodes fall into three categories: 1) the TC is not initiated within 28 days following the PC, 2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which the TC is initiated, even if that date is within 28 days following the PC, or 3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished.

In those cases in which the beneficiary switches providers or stops receiving RT services from the RO participant that initiated the RO episode, the beneficiary would be responsible for 20 percent of the FFS amounts that would have been paid in the absence of the RO Model, unless the RO beneficiary no longer has traditional FFS Medicare. In those cases, the beneficiary is responsible for 20 percent of the first installment of the episode payment amount.

Model Exemptions

CMS finalized its decision not to establish a hardship exemption for RO participants under the RO Model. According to the final rule, the Agency believed that the pricing methodology, which is based on historical rates and recognizes practices' efficiencies, does not represent a significant burden for practices and thus does not warrant any type of hardship exemption. However, radiation oncology centers in Maryland, Vermont or in US Territories are excluded from the model, as are Ambulatory Surgical Centers (ASC), Critical Access Hospitals, PPS-exempt Cancer hospitals, and Pennsylvania Rural Health Model participants, due to their unique payment systems.

ASTRO remains concerned about the lack of a hardship waiver, particularly for small and/or rural practices that demonstrate financial hardship and those severely impacted by the pandemic. ASTRO urged the Agency to establish parameters for hardship exemptions for these practices as well as those that services provided to socioeconomically disadvantaged populations, as these practices tend to have higher cost of care due to patients presenting with advanced disease that is often due to the lack of access to preventative services.

CMS makes no modifications in the final rule to address practice financial hardships. However, the Agency does establish a low volume opt-out option. This allows a PGP, freestanding radiation therapy center, or HOPD, which would otherwise be required to participate in the RO Model, the opportunity to opt-out of the model on an annual basis if the practice furnishes fewer than 20 episodes across all CBSAs selected for participation in the most recent calendar year with available claims data. While the opt-out option is a step in the right direction, ASTRO remains concerned that CMS does not fully understand the challenges that some radiation oncology practices face due to financial hardships, particularly those in rural areas.

Prospectively Paid 90-day Episode

CMS finalized its proposal establishing 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. The 90-day episode 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. To disincentivize the extension of a treatment course beyond the 90-day episode window, CMS establishes 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 Fee-For-Service (FFS) billing rules.

In the final rule, CMS seeks to address concerns regarding those episodes of care that may involve patients receiving treatment for secondary diagnoses identified after the initial diagnosis, but requiring treatment during the 90-day episode. CMS reiterated in the final rule that an RO Episode includes all radiation therapy services furnished to an RO beneficiary with an included cancer type during the 90-day episode of care. If an RO episode includes services for different cancer types, included in the Model, those services and their costs are included in the calculation of the payment rate for that episode. The Agency goes on to provide additional clarification that cancer types are assigned to an episode based on frequency of claims, basically establishing three buckets based on claims data:

1) If two or more claim lines fall within brain metastases or bone metastases or secondary malignancies the episode is set to the cancer type with the highest claim count.

2) If there are fewer than two claim lines for brain metastases, bone metastases or secondary malignancies, the episode is assigned to the cancer type with the highest claim count among all other cancer types. The episode is excluded from the model if the cancer type with the highest claim count is not included in the list of included cancers.

3) If there are no claim lines with cancer diagnosis meeting the previous criteria, then non-cancer type is assigned to that episode and the episode is excluded from the model.

Services Provided by Multiple Physicians

In the proposed rule, it was not clear how the RO Model would recognize services delivered by multiple physicians at different sites of service. These types of scenarios are not uncommon in radiation oncology, particularly in circumstances when both external beam radiation therapy (EBRT) and brachytherapy are used to treat cervical cancer. ASTRO urged the Agency to clarify how it would 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. ASTRO recommended that the services of a second physician be paid at FFS.

In the final rule, CMS states that when the PC component of RT services are provided by more than one Professional participant or Dual participant or when the TC is provided by more than one Technical

participant or Dual participant, these scenarios are considered duplicate services. The RO beneficiary remains under the care of the RO participant that initiated the PC and/or TC. The RO participant(s) that bills the Start of Episode (SOE) and End of Episode (EOE) claims will receive the bundled payment and the RT provider and/or RT supplier furnishing one or more duplicate RT services will bill claims using the designated modifier or condition code to indicate that they should be paid FFS. More information regarding the participation of multiple providers and sites of service will be provided in forthcoming CMS billing and coding guidance.

Additionally, in response to the RO Model proposed rule, radiation oncology stakeholders questioned how a Professional participant who is selected in the Model via an included ZIP code but who furnishes RT services at an exempt facility is to bill for those encounters. In response to this, CMS will use an established modifier for professional claims and a condition code for HOPD claims to indicate that certain services fall outside of the RO episode and should be paid FFS. When services are delivered by a participant and a non-participant they are considered incomplete episodes.

Information, including billing instructions, for billing RT services during the Model performance period are forthcoming. ASTRO will continue to monitor the RO Model website and alert members when this information becomes available.

Cancer Type

In the final rule, CMS modified the list of disease sites included in the RO Model. Initially, the Agency had proposed the inclusion of 17 disease sites. In the final rule, the Agency removed kidney cancer due the fact that kidney cancer is not commonly treated with radiation therapy and therefore does not meet the criteria for inclusion.

Below is the final list of disease sites and corresponding ICD-10 codes included in the RO Model.

Cancer Types and Corresponding ICD-10 Codes	
CANCER_TYPE	**ICD-10 Codes**
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.5x
Brain Metastases	C79.3
Breast Cancer	C50.x, D05.xx
CNS Tumor	C70.xx, C71.xx, C72.xx
Cervical Cancer	C53.xx
Colorectal Cancer	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.x, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Liver Cancer	C22.xx, C23.xx, C24.xx
Lung Cancer	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4xx
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

ASTRO and other radiation oncology stakeholder groups recommended that the Agency exclude liver cancer. CMS decided to retain liver cancer, but it is excluding Yttrium-90 from the RT services included in the list of RO Bundled HCPCS based on ASTRO's recommendation.

Included Services

In the RO Model final rule, CMS establishes that the model will include treatment planning; dose planning; radiation physics and dosimetry, treatment devices, and special services; treatment delivery; and treatment management. A table listing the HCPCS codes included in the RO Model can be found on page 8.

In the proposed rule, the Agency proposed excluding evaluation and management (E/M) services, as well as low volume services from the model, including certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. In the final rule, CMS finalized those exclusions, but adds HCPCS CPT codes 77387 *Guidance for localization of target volume, includes intrafraction tracking if performed*, 77424 *IORT delivery, x-ray, single treatment session*, 77425 *IORT delivery, electrons, single session treatment*, and 77469 *Intraoperative treatment management* to the list of excluded services. Two brachytherapy codes, C1715 and C1728 were also removed from the list.

CMS explained that CPT code 77387 *Guidance for localization of target volume, includes intrafraction tracking if performed* was inadvertently added to the list of included services in the proposed rule. The Model only includes those services paid separately. CPT code 77387 is not paid separately, thus it does not meet the criteria and has been removed from the final list of included services.

The IORT delivery and management codes were removed from the list due to the Agency's decision to remove that modality of treatment from the RO Model. CMS determined that IORT is not a standard approach to treatment and by including it in the model there may be an incentive to misuse the treatment, due to its low cost.

The Agency, in the proposed rule, considered excluding brachytherapy sources due to evidence that physicians sometimes contract with others to supply or administer brachytherapy sources or radioisotopes. ASTRO urged the Agency to exclude brachytherapy sources citing Section 1833(t)(2)(H) of the Social Security Act, which requires that brachytherapy source payments be made separately from professional services. Additionally, ASTRO asserted that 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. Despite ASTRO's argument for exclusion, CMS decided to include brachytherapy sources, in the RO Model, since hospitals are usually the purchasers of the radioactive elements that are generally furnished in HOPDs; however, any services delivered in an Ambulatory Surgical Center are to be excluded.

ASTRO sought clarification regarding whether brachytherapy insertion codes were included in the Model. ASTRO indicated support for their inclusion and CMS confirmed that the brachytherapy insertion codes were included in the final rule.

The list of RO Model bundled HCPCS codes included in the final rule follows:

LIST OF RO MODEL BUNDLED HCPCS			
HCPCS	**HCPCS Description**	**HCPCS**	**HCPCS Description**
55920	Placement Pelvic Needles/Catheters, Brachytherapy	77761	Apply intrcav radiat simple
57155	Placement Tandem and Oviods, Brachytherapy	77762	Apply intrcav radiat interm
57156	Placement Vaginal Cylinder, Brachytherapy	77763	Apply intrcav radiat compl
58346	Placement Heyman Capsules, Brachytherapy	77767	Hdr rdncl skn surf brachytx
77014	CT guidance for placement of	77768	Hdr rdncl skn surf brachytx
77021	MRI guidance for needle placement	77770	Hdr rdncl ntrstl/icav brchtx
77261	Radiation therapy planning	77771	Hdr rdncl ntrstl/icav brchtx
77262	Radiation therapy planning	77772	Hdr rdncl ntrstl/icav brchtx
77263	Radiation therapy planning	77778	Apply interstit radiat compl
77280	Set radiation therapy field	77789	Apply surf ldr radionuclide
77285	Set radiation therapy field	77790	Radiation handling
77290	Set radiation therapy field	77799	Radium/radioisotope therapy
77293	Respirator motion mgmt simul	A9527	Iodine i-125 sodium iodide
77295	3-d radiotherapy plan	C1716	Brachytx, non-str, gold-198
77299	Radiation therapy planning	C1717	Brachytx, non-str, hdr ir-192
77300	Radiation therapy dose plan	C1719	Brachytx, ns, non-hdr ir-192
77301	Radiotherapy dose plan IMRT	C2634	Brachytx, non-str, ha, i-125
77306	Telethx isodose plan simple	C2635	Brachytx, no-str, ha, p-103
77307	Telethx isodose plan cplx	C2636	Brachy linear, non-str, p-103
77316	Brachytx isodose plan simple	C2638	Brachytx, stranded, i-125
77317	Brachytx isodose intermed	C2639	Brachytx, non-stranded, i-125
77318	Brachytx isodose complex	C2640	Brachytx, stranded, p-103
77321	Special teletx port plan	C2641	Brachytx, non-stranded, p-103
77331	Special radiation dosimetry	C2642	Brachytx, stranded, c-131
77332	Radiation treatment aid(s)	C2643	Brachy, non-stranded, c-131
77333	Radiation treatment aid(s)	C2644	Brachyt cesium-131 chloride
77334	Radiation treatment aid(s)	C2645	Brachytx planar, p-103
77336	Radiation physics consult	C2698	Brachytx, stranded, nos
77338	Design mlc device for IMRT	C2699	Brachytx, non-stranded, nos
77370	Radiation physics consult	G0339	Robot lin-radsurg com, first
77371	SRS multisource	G0340	Robot lin-radsurg fractx 2-5
77372	SRS linear based	G6001	Echo guidance radiotherapy
77373	SBRT delivery	G6002	Stereoscopic x-ray guidance
77385	IMRT dlvr smpl	G6003	Radiation treatment delivery
77386	IMRT dlvr cplx	G6004	Radiation treatment delivery
77399	External radiation dosimetry	G6005	Radiation treatment delivery
77402	Radiation treatment delivery	G6006	Radiation treatment delivery
77407	Radiation treatment delivery	G6007	Radiation treatment delivery
77412	Radiation treatment delivery	G6008	Radiation treatment delivery
77417	Radiology port images(s)	G6009	Radiation treatment delivery
77427	Radiation tx management x5	G6010	Radiation treatment delivery
77431	Radiation therapy management	G6011	Radiation treatment delivery
77432	Stereotactic radiation trmt	G6012	Radiation treatment delivery
77435	SBRT management	G6013	Radiation treatment delivery
77470	Special radiation treatment	G6014	Radiation treatment delivery
77499	Radiation therapy management	G6015	Radiation tx delivery imrt
77520	Proton trmt simple w/o comp	G6016	Delivery comp IMRT
77522	Proton trmt simple w/comp	G6017	Intrafraction track motion
77523	Proton trmt intermediate	Q3001	Brachytherapy radioelements
77525	Proton treatment complex		

Included Modalities

CMS finalized its proposal to include all modalities of treatment, with the exception of IORT. The RO Model final rule includes external beam therapy: three-dimensional conformal radiotherapy, intensity-modulated radiotherapy, stereotactic radiosurgery, stereotactic body radiotherapy, and proton beam therapy; image guided radiation therapy; and brachytherapy. In response to stakeholder concerns regarding the inclusion of proton beam therapy, CMS states that its approach to the calculation of participant-specific episode payment amounts places a greater weight on an individual entity's historical experience. Additionally, the Agency points out that by shifting base period to 2016-2018, the data used to establish the National Base Rates includes more data from a greater number of proton beam therapy centers.

ASTRO expressed concern that the Model did not adequately recognize the implementation of new services lines or acquisition of new equipment and urged the Agency to modify the Model to include a rate review mechanism that would allow for the inclusion of the costs associated with these new services. In the final rule, the Agency stated that the Trend Factor will reflect updates to input prices as reflected in updated PFS and OPPS rates. Prospective payments, in general, are not designed to reflect specific investment decisions of individual providers and suppliers, such as practice specific technology acquisition, the Agency said. CMS added that a rate review mechanism is not practical at this time. The Agency did commit to monitoring the adequacy of payments over time, including the Trend Factor, and consider re-baselining in later performance years if analysis indicates it is necessary.

ASTRO urged CMS to pay FFS for any new technology identified by a new CPT code or new technology code. The Agency confirmed that new technologies and new equipment billed under new HCPCS codes will be paid at FFS rates until those codes are added to the list of included services for the RO Model.

In the proposed rule, CMS considered excluding 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 supported the exclusion, but expressed concern that it may be too strict and potentially limit opportunities that would benefit Medicare FFS beneficiaries. In the final rule, CMS adhered to its proposal to exclude proton beam therapy for this purpose. CMS asserts that the clinical trial exception provides sufficient opportunity for more conclusive evidence to be generated around proton beam therapy in the Medicare population. Furthermore, continuing to gather such evidence in the excepted trials will allow CMS to better address commenters' beliefs about proton beam therapy's long-term benefits. This is the only exclusion for proton beam therapy services, other services delivered utilizing proton beam therapy in designated CBSAs are included in the RO Model.

Episode Payment Construct

CMS finalized its proposal that each episode in the RO Model will have corresponding professional component and technical component 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 will calculate the payment amounts for the professional component (PC) and technical component (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.

In the final rule, CMS also defined the term "participant-specific professional episode payment" as a payment made by CMS to a Professional participant or Dual participant for the provision of the professional component of radiation therapy services furnished to a beneficiary during an episode of care. The term "participant-specific technical episode payment" is defined as a payment made by CMS to a technical or dual participant for the provision of the technical component radiation therapy services to a beneficiary during an episode of care.

In the proposed rule, CMS stated that it would provide RO Model participants with their updated participant-specific professional and technical episode payment amounts 30 days prior to the start of each performance year. ASTRO expressed concern about the short period of time that practices would have between understanding their payment rates and the beginning of the performance period, which left little time to confirm and if necessary, seek modification to the amounts. In the final rule, the Agency announced that, rather than providing estimated payment amounts, it will provide RO participants with their case mix and historical experience adjustments for both the PC and TC in advance of the performance year. According to CMS, there are discrepancies between CMS' estimated payment amounts and what RO Model participants will receive. Therefore, the Agency plans to provide each RO Participant with their case mix and historical experience adjustments for both the professional and technical components 30 days prior to the start of the performance year to which those adjustments will apply.

Payment Methodology

Site Neutral Test

CMS proposed that the RO Model would be a "site neutral test" that would establish a common payment amount for services regardless of where they are furnished. In the proposed rule, the Agency indicated that it believed 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. However, the payment methodology associated with the National Base Rate component of the proposed model was solely based on Hospital Outpatient Prospective Payment System (OPPS) data. According to the proposed rule, the Agency argued that OPPS payments were more stable over a longer period of time and thus had a stronger empirical foundation, because they are derived from hospital cost reports, than those under the Medicare Physician Fee Schedule (MPFS).

ASTRO expressed concern that relying solely on OPPS data did not recognize the value of services in the freestanding setting, particularly the Professional Costs associated with each of the disease sites, and undervalued the PC rates for several disease sites in the proposed rule. Additionally, ASTRO disagreed with the Agency's assertion that MPFS rates were unstable. In fact, rate stability has been achieved due

to the payment freeze set forth in the Patient Access and Medicare Protection Act (PAMPA), which overlaps with the RO Model historical data period of 2015-2017.

In the final rule, CMS has finalized its decision to establish a site neutral payment model based on HOPPS payments. The Agency continues to believe that these payments are more stable, despite evidence to the contrary. The Agency is updating its historical base period from 2015-2017 in the proposed rule to 2016-2018 in the final rule.

The RO Model payment methodology consists of eight distinct steps. The first two steps, the National Base Rate and Trend Factor, account for 10 percent of the disease site specific PC and TC payment rate for participating practices. The third step involves a geographic adjustment to account for practice location. The geographic adjustment was designated as the sixth step in the proposed rule, but in the final rule, the Agency has moved it to the third step, where it adjusts the National Base Rate before that amount is blended with practice historical data. The fourth step is the Case Mix Adjustment, Historical Adjustment and Efficiency Factor, which are the practice historical data points that account for 90 percent of the disease site specific PC and TC payment rate for participating practices. Steps five and six account for discounts and withholds that establish nominal amounts at risk and payment based on quality measures, as required by MACRA. The remaining steps, seven and eight, involve co-insurance, which is set at 20 percent of the payment rate, and sequestration.

In the final rule, CMS establishes a stop-loss limit of 20 percent for RO participants that have fewer than 60 episodes in the baseline period between 2016-2018. The stop-loss limit will be applied to those RO participants who do not qualify to receive a historical experience adjustment and may see greater increase or reductions compared to what they were historically paid under FFS. Using no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the Model, CMS will pay these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS. Payments under the stop-loss policy are determined at the time of reconciliation.

Below is a detailed analysis of each component of the payment methodology:

<u>Step 1: National Base Rates</u>

CMS proposed to establish National Base Rates based on data from 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. As previously noted, ASTRO expressed concern regarding the exclusion of MPFS historical rates in the National Base Rate PC calculation for each disease site. Additionally, based on an analysis of the National Base Rates found in the proposed rule, ASTRO discovered that CMS had included palliative care cases for each disease site.

ASTRO urged the Agency to establish business rules that would be applied to the National Base Rates that would include MPFS payment rates in the PC component and remove the palliative care cases, from both the PC and TC calculations, and create a separate “Cancer Symptom Palliation, Not Otherwise Specified” episode to capture palliative care cases and ensure their inclusion in the model. This would ensure accurate payment for curative cases versus palliative cases.

In the final rule, the Agency rejected ASTRO's recommended use of MPFS rates for the PC component to the National Base Rates. The Agency stated that MPFS rates have been stable since 2015, but asserted that recent stability was only due to the actions of ASTRO and others. Additionally, the Agency clarified that while the National Base Rates in the RO Model are calculated based on episodes occurring in the HOPD setting, the episodes include payments made to physicians under the MPFS for the PC and payments to freestanding radiation therapy centers for the TC in episodes where beneficiaries sought treatment from both HOPDs and freestanding radiation therapy centers. ASTRO is concerned that the Agency is relying on data from a limited number of cases that involve two sites of service, which has the potential to distort the rates for the PC component for each disease site.

Additionally, the Agency did not establish separate episodes for palliative care stating that it could not determine if a treatment was palliative in nature based on a count of fractions. Additionally, the Agency asserted that tying episode payment to fraction count retains the FFS-incentive structure and potentially removes cases in which curative treatment included a low number of fractions.

The Agency also did not modify the payment methodology for cervical cancer. ASTRO expressed concern in the proposed rule that the National Base Rates were based on CMS data files that indicated that, of the 2,946 cervical cancer episodes that occurred between 2015-2017, only 629 of the episodes were treated with combination EBRT and brachytherapy—which is the guideline concordant standard of care for the treatment of cervical cancer. For these 629 episodes provided with guideline concordant care, ASTRO found that 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, ASTRO expressed concern that proposed episode-based payment rates included data based on the HOPPS C-APC methodology, which has been demonstrated to undervalue treatment for cervical cancer.

In the final rule, the National Base Rates are set at $3,829 and $17,581 for the PC and TC respectively based on data from the 2016-2018 base line period. While these rates are an increase over the proposed rule rates, ASTRO remains concerned that the cervical cancer episode is undervalued, and since cervical cancer is predominantly seen in women with poor access to health care further widens the health care discrepancies for socioeconomically disadvantaged. Additional analysis indicated a significant portion of cervical cancer cases involved multiple physicians, as well as the greatest number of site of service shifts from freestanding to HOPD and vice versa of all disease sites included in the model. CMS justified the final payment rate for cervical cancer by saying that it had reviewed the C-APC methodology for brachytherapy and cervical cancer and determined that it provides appropriate payment, despite clear evidence to the contrary. Since the delivery of appropriately applied brachytherapy is crucial to curative therapy and takes special expertise, this underpayment will continue to result in women receiving substandard care and unfairly disadvantage women.

Below is a chart depicting the National Base Rates found in the proposed rule compared with ASTRO's recommendations and the rates in the Final Rule.

	PROFESSIONAL COMPONENT			TECHNICAL COMPONENT		
CANCER_TYPE	CMS PROPOSED AMOUNT	ASTRO PROPOSED AMOUNT	FINAL RULE	CMS PROPOSED AMOUNT	ASTRO PROPOSED AMOUNT	FINAL RULE
Anal Cancer	$2,968	$3,125	**$3,001**	$16,010	$16,488	**$ 16,544**
Bladder Cancer	$2,637	$3,123	**$2,688**	$12,553	$14,432	**$ 13,292**
Bone Metastases	$1,372	$1,443	**$1,398**	$5,561	$5,561	**$ 5,972**
Brain Metastases	$1,566	$1,591	**$1,602**	$9,217	$9,217	**$ 9,649**
Breast Cancer	$2,075	$2,180	**$2,081**	$9,739	$9,739	**$ 10,129**
CNS Tumor	$2,463	$2,534	**$2,511**	$14,194	$14,194	**$ 14,711**
Cervical Cancer	$3,780	$4,071	**$3,829**	$16,944	$18,205	**$ 17,581**
Colorectal Cancer	$2,369	$2,654	**$2,449**	$11,590	$12,743	**$ 12,040**
Head and Neck Cancer	$2,946	$3,091	**$3,019**	$16,710	$17,132	**$ 17,485**
~~**Kidney Cancer**~~	~~$1,551~~	~~$1,570~~	**NA**	~~$7,659~~	~~$7,659~~	***NA***
Liver Cancer	$1,517	*NA*	**$2,082**	$14,654	*NA*	**$ 11,976**
Lung Cancer	$2,155	$2,448	**$2,181**	$11,451	$12,976	**$ 11,994**
Lymphoma	$1,662	$1,720	**$1,690**	$7,444	$7,444	**$ 7,855**
Pancreatic Cancer	$2,380	$2,466	**$2,394**	$13,074	$13,074	**$ 13,384**
Prostate Cancer	$3,228	$3,777	**$3,260**	$19,876	$21,355	**$ 20,249**
Upper GI Cancer	$2,499	$2,772	**$2,586**	$12,615	$13,843	**$ 13,530**
Uterine Cancer	$2,376	$2,538	**$2,436**	$11,223	$11,613	**$ 11,869**
~~**Cancer Symptom Palliation, Not Otherwise Specified**~~	~~*NA*~~	~~$1,147~~	NA	~~*NA*~~	~~$3,984~~	NA

Step 2: Application of a Trend Factor

The second step involves the application of a trend factor that is designed to account for trends in payment rates and volumes for radiation therapy services outside of the Model under the Hospital Outpatient Prospective Payment System and the Medicare Physician Fee Schedule. The calculation involves the average number of times each HCPCS code was furnished for the most recent calendar year with complete data. The Trend Factor will be updated and applied each year to both the PC and TC of each cancer type.

For both the PC and TC, the Agency finalized its decision to calculate the ratio of: a) volume-weighted FFS payment rates for radiation therapy services included in that component for each specific cancer type in the upcoming participation year (numerator) to b) volume-weighted FFS payment rates for RT services included in that component for each cancer type in the most recent base line year (denominator). Any new codes that are introduced are proposed to be cross-walked to volumes based on existing code sets.

In the final rule, CMS finalized the Trend Factor calculation for PY1 as follows:

$$\text{2021 Trend Factor} = \frac{\text{(2018 volume * 2021 corresponding FFS rates as paid under OPPS or PFS)}}{\text{(2018 volume*2018 corresponding FFS rates as paid under OPPS or PFS)}}$$

In the final rule, CMS clarified that the denominator used to determine the average number of times each HCPCS code and corresponding FFS payment rate do not change over the Model's performance period. Therefore, the 2018 volume weights and payment rates included in the payment methodology

will not change unless the Agency proposes to rebase the payment methodology, which it would do through future rulemaking. However, the volume weights and payment rates in the numerator are updated every year to the most recent year's available data.

ASTRO expressed concern in a letter issued to the Agency in July regarding the impact of COVID-19 on the RO Model, including the Trend Factor, which was expected to use 2020 volume data in the 2023 Trend Factor methodology. The decline in 2020 patient volumes as a result of delays in care due to COVID-19 will have a negative effect on the calculation of the RO Model Trend Factor. In the final rule, CMS acknowledged this concern and indicated that it will review utilization data in non-RO participants' 2020 episodes to assess the impact of the PHE on RT treatment patterns and whether an alternative method is needed to keep the trend factor for PY 3 from being artificially low or high due to the PHE. Any resulting changes will be considered in future rulemaking.

Step 3: Geographic Adjustments

In the third step, CMS finalized the application of a geographic adjustment to payments for local cost and wage indices based on where the radiation therapy services are delivered, pursuant to existing geographic adjustment processes in the OPPS and MPFS. The OPPS automatically applies a wage index adjustment; however, the MPFS geographic adjustment is applied to three separate components, work, practice expense and malpractice.

In the proposed rule, the application of the Geographic Adjustments was the sixth step in the payment methodology. In the final rule, CMS has modified the order of the payment methodology so that the geographic adjustment is applied to the trended National Base Rates prior to the case mix and historical experience adjustments. CMS notes that modifying the sequence of the pricing methodology in this way changes the amount of dollars attributed to the discount factor and each withhold, however it does not change the participant specific professional or technical episode payment amounts.

Additionally, the Agency clarifies that although the RO Model specific RVU values are derived from the national base rates, which are based on the 2016-2018 base period that had the majority of radiation treatment service furnished at an HOPD and that were attributed to an HOPD, the Agency will use only 2018 episodes to calculate the implied RVU shares or the proportional weights of each of the three components. These RVU shares are part of the calculus determining the RO Model specific RVU values.

RVU Shares					
Professional Component			Technical Component		
WORK	PE	MP	WORK	PE	MP
0.66	0.3	0.04	0	0.99	0.01

Step 4: Case Mix, Historical Experience, and Efficiency Adjustments

In the fourth step, the Agency adjusts the National Base Rates to account for each RO participant's case mix, historical experience, and efficiency. This component of the payment methodology was designed to account for 90 percent of the episode case rate (with 10 percent attributed to the National Base Rate

as described above) before the application of discounts, withholds and other adjustments described in subsequent steps.

The case mix adjustment was designed to account for care patterns and factors that are beyond the RO participant's control, which 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 Agency proposed using a Winsorization process to cap episode payments attributed to the RO participant at the 99th and 1st percentiles. It then compared a RO participant's predicted payments, which recognize case mix, to a RO participant's expected payments, which do not consider case mix. The difference between a RO participant's predicted payment and expected payment divided by the expected payment yields either the PC or TC case mix adjustment for the RO participant.

The historical experience adjustment was proposed to include episode data attributed to the RO participant during 2015-2017. The methodology for the historical experience adjustment was proposed to be similar to the Case Mix Adjustment methodology in that it uses a Winsorization process to cap episode payments, but it does not vary by cancer type. The historical experience adjustment for the PC and TC component would be the difference between: the sum of a) Winsorized payments for episodes attributed to the radiation oncology participant and b) the summed predicted payments from the case mix adjustment calculation, which would then be divided by c) the summed expected payments used in case mix adjustment calculations.

In the proposed rule, CMS did not provide any details on the range of predicted and expected payments for a RO participant, or examples of how the methodology would be calculated for a practice. It was ASTRO's understanding that these payments were based on National Base Rate data, thus including only HOPD data, disregarding the differences in case mix between freestanding and hospital-based practices, which can vary significantly. ASTRO urged CMS to use a blended MPFS/OPPS methodology, which yields a predictive value closer to 1; however, the Agency did not incorporate this recommendation nor provide an explanation.

Additionally, ASTRO raised concern in a July 2020 letter that the Case Mix Adjustment methodology is based on pre-COVID-19 Case Mix Adjustment variables from the historical baseline. Due to COVID-19, many patients have delayed diagnostic tests and cancer treatment, thus making the case mix variables a potentially unreliable predictor of fee-for-service costs post-COVID-19. Delayed testing and treatment are expected to result in patients presenting with advanced stage disease requiring more complex and expensive treatment in the future[1]. The impact of COVID-19 on practice specific patient case mix will not appear until 2021. Because of delays in data collection associated with payment models, those data points would not be folded into the RO Model case mix methodology until PY4 (2024). ASTRO urged CMS to consider a COVID-19 adjustment that would be made to the Case Mix Adjustment methodology so that the impact of COVID-19 could be recognized more immediately in the payment methodology. The final rule was silent on this issue.

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

CMS finalized the Case Mix and Historical Experience Adjustments as proposed, with a modification to derive calculations based on episodes from the same period, 2016-2018, used to derive the National Base Rates. Additionally, CMS provides more clarification and tries to simplify the process for calculating the expected payment for each RO participant, rather than using average Winsorized episode payments for each cancer type, as proposed. The Agency will develop a second regression model that calculates expected payment amounts based on cancer type alone. According to CMS, this will align with the use of regression models in the numerator and denominator of the case mix calculation. For a given RO participant, the difference between predicted episode payment amounts from the first regression model and the expected payment amounts from the second regression model, which is then divided by payment amounts, represents the net impact of demographics, presence of chemotherapy, presence of major procedures, and death rates on episode payment amounts for that RO Participant. The Case Mix Adjustment will be updated for each RO Participant annually, based on a three-year rolling period of episodes attributed to the RO participant that will be input into the case mix regression model. Finally, the Agency committed to providing examples of how the Case Mix and Historical Experience Adjustments are calculated on the RO Model website.

The historical experience adjustment was proposed to be further weighted by an efficiency factor that was purported to measure whether a RO participant's episodes have historically been more or less costly than the National Base Rate. ASTRO's analysis of the efficiency factor indicated that it had the potential to harm efficient practices. In response to the proposed rule, ASTRO urged the Agency to modify the Efficiency Factor so that it protects efficient practices from any financial instability associated with the transition to value based payment.

In the final rule, CMS is renaming the Efficiency Factor, the "Blend." CMS believes that the new moniker clarifies what the calculation represents. The Agency asserts that removal of the efficiency factor or blend for efficient providers and suppliers prevents the Model from maintaining costs or achieving savings. CMS points to the chart on page 17 entitled "Efficient (Historical Experience Adjustment ≤0.0" to demonstrate that efficient providers will earn more than their current average, thus ensuring that they are able to maintain current costs while also achieving savings under the Model.

In Table 4 of the Final Rule, CMS estimates the break-down between efficient and inefficient practices, as well as those with fewer than 60 attributed episodes in the baseline which are assigned a Historical Experience Adjustment of 0.0.

	Professional	Technical
Efficient (Historical Experience Adjustment <0.0)	25.6%	36.2%
Inefficient (Historical Experience Adjustment >0.0)	49.9%	27.6%
Neither (Historical Experience Adjustment = 0.0)	24.5%	36.2%

CMS provides examples in the proposed rule of the impact of the Blend on efficient and inefficient practices that are replicated below.

Efficient (Historical Experience Adjustment ≤ 0.0)	
National Base Rate	$15,000
RO Participant 1 Average	$14,000
90/10 (PY1-PY5)	$14,100

Inefficient (Historical Experience Adjustment ≥ 0.0)	
National Base Rate	$ 15,000
RO Participant 2 Average	$ 30,000
90/10 (PY1)	$ 28,500
85/15 (PY2)	$ 27,750
80/20 (PY3)	$ 27,000
75/25 (PY4)	$ 26,250
70/30 (PY5)	$ 25,500

Inefficient (Historical Experience Adjustment ≥ 0.0)	
National Base Rate	$ 15,000
RO Participant 3 Average	$ 20,000
90/10 (PY1)	$ 19,500
85/15 (PY2)	$ 19,250
80/20 (PY3)	$ 19,000
75/25 (PY4)	$ 18,750
70/30 (PY5)	$ 18,500

According to CMS, the use of historical payments to determine efficiency is an appropriate basis for comparison, which will allow efficient practices to experience an increase in payment. In contrast, historically inefficient practices will experience incremental decreases in payments over the Model's performance period as the National Base Rates account for a greater portion of practice payment over time. Furthermore, the Agency asserts that the RO Model is not designed to create equal rates for all RO participants but rather create participant-specific professional and technical episode payment amounts that draw RO participants as a group toward an average payment over time.

ASTRO remains concerned that there have been no modifications to the methodology to ameliorate the potential negative impact that the methodology may have on efficient practices. Additionally, despite ASTRO's concern that the methodology does not account for those situations in which a patient requires a more expensive modality of treatment due to unique clinical indications, CMS asserts that the Case Mix and Historical Experience Adjustment account for beneficiaries who require more expensive or frequent treatments. As stated in the ASTRO comment letter, if the Agency's intent is to merely cut costs and disregard the quality of patient care, then this provision satisfies that goal.

Below is a summary of the Adjustment Factor Calculations included in the Final Rule:

Case Mix Adjustment = (predicted payment – expected payment)/expected payment

Historical experience adjustment = Winsorized payments – predicted payments)/expected payments

Efficiency Factor:
Winsorized episode payments > predicted payments = 0.90 (PY1), 0.85 (PY2), 0.80 (PY3), 0.75 (PY4), 0.70 (PY%)

Winsorized episode payments ≤ predicted payments = 0.90 (PY1-PY5)

Combined Adjustment = (Historical experience adjustment * Efficiency Factor) + Case Mix Adjustment + 1.0

Step 5: Discount Factor

The fifth step involves a discount factor. The Agency proposed a discount factor of 4 percent for the PC and 5 percent for the TC. ASTRO expressed concern that the discount factors, as proposed, represented a significant cut to radiation oncology practices. Combined with the Withholds described in Step 5, they have the potential to put many practices at financial risk, particularly those with thin operating margins. ASTRO urged the Agency to reduce the discount factors to no more than 3 percent for both the PC and the TC payment.

In the final rule, CMS reduces the discount factors by 0.25 percent establishing a discount factor of 3.75 percent for the PC and 4.75 percent for the TC. According to the Agency, the discount factors strike a balance between creating savings for Medicare, while not creating substantial financial burden on radiation oncology participants. ASTRO disagrees completely and believes that the discount factor will prove to be a significant financial burden for practices that are compelled to participate in the model.

Step 6: Withholds for Payment Issues and Quality Measures Performance

In the sixth step, CMS proposed to withhold a percentage of the total episode payments to address payment issues and create quality measure incentives. The Agency proposed 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 was designed to reserve money for purposes of reconciling duplicate radiation therapy services and incomplete episodes during the reconciliation process. A duplicate radiation therapy service is any service that is furnished to a single beneficiary by a radiation therapy provider or supplier that did not initiate the PC or the TC for that episode. An incomplete episode occurs when 1) a Technical participant or a Dual participant do not furnish a technical component to a beneficiary within 28 days following a Professional participant or Dual participant furnishing a treatment planning service, or 2) when traditional Medicare stops being the primary payer, or 3) a beneficiary stops meeting the beneficiary criteria. The annual reconciliation process, which was proposed to take place 20 months after the end of the performance period, would be used to determine whether a radiation oncology participant is eligible to receive back the full 2 percent withhold amount, a portion of it, or must repay funds to CMS.

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 PY3, to the technical component to account for patient satisfaction with care. Technical participants and Dual participants would be able to earn back up to the full amount of the withhold based on their results from the patient-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey for Radiation Therapy.

In response to the proposed rule, ASTRO was greatly concerned that the discount factors in combination with the withholds would create significant financials stress for many practices, not only due to the significant reductions in payment but also due to the fact that the withholds would be retained through a 20-month long reconciliation period.

In the final rule, the Agency retains the withholds for incorrect payments and quality measures but reduces the incorrect payment withhold to 1 percent. According to the final rule, CMS states that the reduction of this withhold will ease the burden of keeping up with the dept service, while retention of the quality withhold will incentivize RO participants to provide high quality care. The Agency also indicated that it will reevaluate the incorrect payment withhold amount in PY3.

Step 7: Coinsurance

In the seventh step, CMS proposed that Medicare beneficiaries would pay 20 percent of each of the bundled PC and TC payments for their cancer type. ASTRO expressed concern that by retaining the existing 20 percent coinsurance requirement some beneficiaries would pay more for care than they would outside the model. ASTRO urged CMS to 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 percent 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, ASTRO asserted that 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 did not recognize or address the role of Medigap as a secondary payer. ASTRO urged 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 recommended 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 RO Model.

In the final rule, CMS disregarded concerns about the potential financial burden that the RO Model may impose on some Medicare FFS beneficiaries. The Agency reasserted its recommendation that RO Participants implement payment plans to address these concerns. CMS also stated that for secondary payers, the Agency will provide RO Model specific information, including how the RO Model specific HCPCS codes will be processed.

Step 8: Sequestration

In the last step of the payment methodology, CMS finalized the inclusion of a 2 percent adjustment for sequestration in the RO Model payment methodology. The sequestration adjustment is required by law and applies to billed RO Model specific services.

The table below summarizes the data sources and time periods used to determine values for each of the RO Model's key pricing components.

Table 10: DATA SOURCES AND TIME PERIODS USED TO DETERMINE VALUES OF THE RO MODEL'S KEY PRICING COMPONENTS

Key Components	Data Source	PY1 (2021)	PY2 (2022)	PY3 (2023)	PY4 (2024)	PY5 (2025)
National Base Rates	HOPD Episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Trend Factor	Non-participant episodes	(2018 volume*2021 rates)/(2018 volume*2018 rates)	(2019 volume*2022 rates)/(2018 volume*2018 rates)	(2020 volume*2023 rates)/(2018 volume*2018 rates)	(2021 volume*2024 rates)/(2018 volume*2018 rates)	(2022 volume*2025 rates)/(2018 volume*2018 rates)
Winsorization Thresholds	HOPD Episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Case Mix Coefficients	HOPD Episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Case Mix Values [and whether eligible (>60 episodes) to receive case mix adjustment]	Participant Specfic	2016-2018	2017-2019	2018-2020	2019-2021	2020-2022
Historical Experience Adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant Specfic	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Blend for RO Participant with historical experence adjustment > 0.0	N/A	0.90	0.85	0.80	0.75	0.70
Blend for RO Participant with historical experence adjustment ≤ 0.0	N/A	0.90	0.90	0.90	0.90	0.90
RVU Shares used in the PFS geographic adjustment	HOPD Episodes	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2018	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2018	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2018	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2018	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2018
Low Volume Opt-Out Eligibility (<20 episodes)	Participant Specfic	2019	2020	2021	2022	2023

The following tables detail the payment methodology for the PC and TC component of a Lung Cancer Case. The numbers used are for illustrative purposes only.

PARTICIPANT SPECIFIC PROFESSIONAL EPISODE PAYMENT FOR LUNG CANCER PY1		
	Amount	Formula
National Base Rate	$ 2,181	National Base Rate for Lung Cancer - PC Payment
Trend Factor	1.04	TF=(2018 Volume*2021 Rates)/(2018 Volume*2018 Rates)
Subtotal A	$2,268.24	Subtotal = National Base Rate (Trend Factor)
SPLIT for SOE/EOE	$1,134.12	SPLIT = Subtotal /2
Geographic Adjustment	1.02	>1 = high cost area, <1 = low cost area
Subtotal B	$1,156.80	Subtotal = SPLIT *Geographic Adjustment
Case Mix Adjustment	0.02	CMA = (Predicted Payment - Expected Payment)/Expected Payment
		CMA = (102-100)/100
Historical Adjustment	0.14	HEA = (Winsorized Payments - Predicted Payment)/Expected Payment
		HEA = (116-102)/100
PY1 Blend	0.90	0.9 for all RO Participants in PY 1[V]
Adjustments Combined	1.15	Combined Adjustment = CMA + (HEA*Efficiency Factor) + 1.0
		Combined Adjustments = 0.02 + (0.14*0.90) + 1.0
Subtotal C	$1,325.70	Subtotal C = Adjustments Combined * Subtotal B
Discount Factor	0.0375	
Subtotal D	$1,275.98	Subtotal D = (1-Discount Factor) *Subtotal C
Withhold - Incorrect Payment	0.01	
Withhold - Quality Performance	0.02	
Total Withhold	0.03	Total Withhold = Incorrect Payment Withhold + Quality Performance Withhold
Half of Total Episode Payment to RO Participant without sequestration	$1,237.70	Half of Total Episode Payment Without Sequestration = (1-Total Withhold)*Subtotal D)
Beneficiary Coinsurance for SOE payment determined	$ 247.54	Beneficiary Coinsurance for SOE Payment = Half of Total Episode without Sequestration *0.20
SOE Participant Payment	$ 990.16	SOE Participant Payment = Half of Total Epiosde without Sequestration*0.80
Sequestration Claims Payment Adjustment to Participant Payment [half the total participant-specific professional episode payment]	$ 970.36	Sequestration Claims Payment Adjustment to Particpant Payment = SOE Participant Payment*0.98
Episode Payment 1: SOE	$ 970.36	SOE = Sequestration Claims Payment Adjustment to Participant Payment
Episode Payment 2: EOE	$ 970.36	EOE = Sequestration Claims Payment Adjustment to Participant Payment
Total Episode Payment to the RO Participant	$2,435.80	Total Episode Payment to RO Participant = SOE Payment + EOE Payment + 2(Beneficiary Coinsurance for SOE Payment)

[V]The blend rate declines by 0.05 each year for practices deemed inefficient, ie. HEA >0.0

PARTICIPANT SPECIFIC TECHNICAL EPISODE PAYMENT FOR LUNG CANCER PY1		
	Amount	Formula
National Base Rate	$ 11,451	National Base Rate for Lung Cancer - PC Payment
Trend Factor	1.04	TF=(2018 Volume*2021 Rates)/(2018 Volume*2018 Rates)
Subtotal A	$11,909.04	Subtotal = National Base Rate (Trend Factor)
SPLIT for SOE/EOE	$ 5,954.52	SPLIT = Subtotal /2
Geographic Adjustment	1.02	>1 = high cost area, <1 = low cost area
Subtotal B	$ 6,073.61	Subtotal = SPLIT *Geographic Adjustment
Case Mix Adjustment	0.02	CMA = (Predicted Payment - Expected Payment)/Expected Payment
		CMA = (102-100)/100
Historical Adjustment	0.14	HEA = (Winsorized Payments - Predicted Payment)/Expected Payment
		HEA = (116-102)/100
PY1 Blend	0.90	0.9 for all RO Participants in PY 1[V]
Adjustments Combined	1.15	Combined Adjustment = CMA + (HEA*Efficiency Factor) + 1.0
		Combined Adjustments = 0.02 + (0.14*0.90) + 1.0
Subtotal C	$ 6,960.36	Subtotal C = Adjustments Combined * Subtotal B
Discount Factor	0.0475	
Subtotal D	$ 6,629.74	Subtotal D = (1-Discount Factor) *Subtotal C
Withhold - Incorrect Payment	0.01	
Withhold - Quality Performance	0	Not applied until PY3
Total Withhold	0.01	Total Withhold = Incorrect Payment Withhold + Quality Performance Withhold
Half of Total Episode Payment to RO Participant without sequestration	$ 6,563.44	Half of Total Episode Payment Without Sequestration = (1-Total Withhold)*Subtotal D)
Beneficiary Coinsurance for SOE payment determined	$ 1,312.69	Beneficiary Coinsurance for SOE Payment = Half of Total Episode without Sequestration *0.20
SOE Participant Payment	$ 5,250.75	SOE Participant Payment = Half of Total Epiosde without Sequestration*0.80
Sequestration Claims Payment Adjustment to Participant Payment [half the total participant-specific professional episode payment]	$ 5,145.74	Sequestration Claims Payment Adjustment to Particpant Payment = SOE Participant Payment*0.98
Episode Payment 1: SOE	$ 5,145.74	SOE = Sequestration Claims Payment Adjustment to Participant Payment
Episode Payment 2: EOE	$ 5,145.74	EOE = Sequestration Claims Payment Adjustment to Participant Payment
Total Episode Payment to the RO Participant	$12,916.86	Total Episode Payment to RO Participant = SOE Payment + EOE Payment + 2(Beneficiary Coinsurance for SOE Payment)

[V]The blend rate declines by 0.05 each year for practices deemed inefficient, ie. HEA >0.0

Final Professional and Technical Billing and Payment

CMS will prospectively pay the full participant-specific professional and technical episode payments in two installments: one tied to the beginning of the episode and other tied to the end of the episode. Payments for radiation therapy services will be made under existing Medicare payment systems using new RO Model specific HCPCS codes and modifiers indicating the start of an episode (SOE) and the end of an episode (EOE).

The Professional participant or Dual participant that furnishes the PC of the episode will be required to bill one of the new RO Model-specific HCPCS codes and an SOE modifier. This indicates that an episode of care has started and triggers the first payment. In the final rule, CMS modified its policy to allow the RO Participant to submit the RO-Model specific HCPCS code and an EOE modifier claim after the course of RT treatment has ended, but no earlier than 28 days after the initial treatment planning service was

furnished. This is an improvement on the proposed rule which indicated that the EOE claim could not be submitted until the end of the 90-day episode of care.

Radiation oncology participants will be required to submit encounter claims data that include all radiation therapy services identified on the RO Model bundled HCPCS list (page 8) as services are delivered. The encounter data will be used for evaluation and model monitoring, specifically trending the utilization of radiation therapy services.

In the event that a Medicare beneficiary changes their radiation oncology provider after the SOE claim has been paid, CMS will subtract the first episode payment paid to the RO participant from the FFS payments owed to the radiation oncology participant for services furnished to the beneficiary before the transition occurred and listed on the no-pay claims. This will occur during the reconciliation process. CMS proposes to make similar arrangements should the beneficiary die, enter hospice, choose to defer treatment, or if Medicare stops being the primary payer.

If traditional Medicare stops being a beneficiary's primary payer after the TC of the episode has been initiated then, regardless of whether the beneficiary's course of radiation therapy treatment was completed, the 90-day period is considered an incomplete episode and the RO participant may receive only the first installment of the episode payment. In the event that a beneficiary dies or enters hospice during an episode, then the RO participant may receive both installments of the episode payment, regardless of whether the beneficiary's course of radiation therapy has ended.

CMS will issue instructions regarding the new billing and payment policies through Medicare Learning Network (MLN) publications, model specific webinars and on the RO Model website. ASTRO will alert members once these educational tools become available.

Other Model Parameters

Low Volume Practices

In the RO Model final rule, CMS established that if a HOPD or freestanding radiation therapy center provides fewer than 60 attributed episodes during the 2016-2018 period, the radiation oncology participant's participant-specific professional episode payment and technical episode payment amounts would 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.

Application of LCD Policies and Prior Authorization

ASTRO expressed concern in response to the RO Model proposed rule that Medicare Administrative Contractors (MACs) would continue to apply Local Coverage Determination (LCD) policies and other prior authorization tools, which restrict patient-physician decision making. In the final rule, CMS pointed out that the MACs will not have the ability to apply LCDs to RO Model claims because only the RO Model specific HCPCS codes appear on the claim. These codes are not included in any current LCDs. Additionally, the Agency stated that RO Model services are not subject to prior authorization. However,

CMS will monitor utilization of RT services throughout the demonstration period and use the reasonable and necessary provisions as stated in applicable LCDs as a monitoring tool.

Merger, Acquisition, or Other New Clinical or Business Relationship

CMS finalized its decision that a new TIN or CCN that results from a merger, acquisition or other new clinical or business relationship that occurs prior to October 3, 2025, or any new TIN or CCN that begins to furnish radiation therapy services within a selected CBSA be compelled to participate in the RO Model. According to the Agency, this would prevent HOPDs and freestanding radiation therapy centers from engaging in these types of activities to avoid participating the model.

Quality

In the RO Model final rule, CMS finalized the establishment of an Aggregate Quality Score (AQS) that is based on performance on evidence-based quality measures in comparison to those measures' benchmarks; selected patient experience measures; reporting of data for proposed pay-for-reporting quality measures; and reporting of clinical data elements.

Evidence Based Quality Measures

To assess the quality of care provided during an episode of care, the Agency is finalizing the establishment of the following evidence-based quality measures. The Agency believes these measures allow it to quantify the impact of the Model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems.

- Oncology: Medical and Radiation – Plan of care for Pain – NQF #0383; CMS Quality ID #144
- Preventative Care and Screening: Screening for Depression and Follow-Up Plan – NQF #0418; CMS Quality ID #134
- Advance Care Plan – NQF #0326; CMS Quality ID #047
- Treatment Summary Communication – Radiation Oncology

In the proposed rule, CMS did not specify which benchmarks and collection types the Agency planned to use for these measures. ASTRO recommended that MIPS benchmarks and collection types be used to ease transition into the RO Model and align quality reporting programs. In the final rule, CMS clarified that it will use MIPS benchmarks where available, and will develop benchmarks for those measures that do not have MIPS benchmarks. Additionally, the Agency will adopt registry specifications for the Model's measures, which include data collection procedures. CMS committed to aligning the Model measures, benchmarks, and reporting requirements with MIPS when possible.

ASTRO also urged the Agency to allow practices to use relevant third parties for data collection and reporting. In the final rule, CMS stated that it would provide information about the submission of data prior to the PY1 data reporting start date on the RO Model website. This information will include whether the Agency finds it appropriate to allow for third-party data submission.

ASTRO raised concerns that the claims data for the "Preventative Care and Screening: Screening for Depression," and "Advanced Care Plan" is topped out. This means that if a participant chooses to

submit data for either of those measures using the claims data collection type, they will not receive the full 10 points, which puts them at a disadvantage in the overall scoring.

In the final rule, CMS disagreed with ASTRO regarding the topped out status for both measures, stating that the measure is not topped out for the population of providers and suppliers who participate in MIPS and submit their data through the MIPS CQM. Additionally, the Agency asserted that even if the measure were topped out, there is value to implementing measures that have topped out to prevent a decrease in performance in this aspect of care.

ASTRO further noted in response to the proposed rule that the "Plan of Care for Pain" measure was changed for the 2019 MIPS performance year from those who report all pain to those who report moderate to severe pain. The CMS measure steward revised the measure back to the 2018 specifications, which require reporting for all pain in 2020. In the final rule, CMS acknowledged that measure specifications change over time and confirmed that the Agency would use the most recent measure in the RO Model.

For the "Treatment Summary Communication" measure, CMS proposed use of the measure if it were changed from four to two weeks. ASTRO and other radiation oncology stakeholders urged the Agency to use the original four-week specification. In the final rule, CMS again stated that where one measure is being used in multiple CMS programs or models, the Agency will seek to align measure specifications and use the most up-to-date version as appropriate.

CAHPS Cancer Care Survey

In addition to the quality measures described above, CMS finalized the inclusion of selected patient experience measures based on the CAHPS Cancer Care Survey. Survey data will be incorporated into the AQS for Professional and Dual participants beginning in performance year 3. For 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 above.

In future rulemaking, the Agency plans to propose a set of patient experience measures based on the CAHPS Cancer Care Survey, which would be included in the AQS as pay-for-performance measures beginning in performance year 3.

Data Collection Process

In the RO Model proposed rule, CMS proposed reporting requirements involving aggregated quality measure data, instead of beneficiary-level quality measure data. Additionally, the Agency proposed requiring that data be reported to include all applicable patients (not just Medicare beneficiaries) based on the numerator and denominator specifications for each measure. CMS asserted 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 beneficiaries, is appropriate because it is consistent with the applicable measure specifications, and any segmentation to solely the Medicare

populations would be inconsistent with the measure and add a substantial reporting burden to RO participants.

While ASTRO appreciated the intent of reducing burden, it was unclear how CMS would implement this requirement to ensure that burden reduction is achieved. ASTRO asserted in response to the proposed rule that reporting for all patients was 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. ASTRO urged the Agency to modify the proposal to require reporting just on those Medicare FFS beneficiaries who are participating in the model.

CMS finalized its proposal to require reporting of aggregated quality for all patients as defined in measure specifications. The process for submitting data through the RO Model secure data portal will be provided via technical support and educational efforts that will take place in the coming weeks. Announcements regarding these tools will be posted on the RO Model website. ASTRO will monitor these announcements and alert members once they are posted.

Finally, CMS will provide Professional participants and Dual participants with a mechanism to input quality measure data, including a secure portal for data submission. ASTRO urged the Agency to use the same reporting mechanisms that practices currently use for the MIPS program. Additionally, ASTRO expressed concern that hospital-based practices may face reporting barriers as there is no requirement that hospitals modify their reporting systems to accommodate RO Model quality measures reporting. In the final rule, CMS disregarded these recommendations and finalized the process for submitting data through the RO Model secure data portal. More information regarding the portal will be issued in forthcoming communications from the Agency.

<u>Proposed Clinical Data Element (CDE) Collection</u>

In addition to collecting quality measures data, CMS also proposed the collection of basic clinical information, not available on claims or captured in quality measures, on Medicare beneficiaries treated for prostate, breast, lung, bone metastases, and brain metastases. The clinical data element (CDE) collection requirement was proposed to be a pay for reporting requirement applied to Professional participants and Dual participants. CMS proposed to use the data to support clinical monitoring and evaluation of the RO Model. The Agency did not define the specific data elements and reporting standards in the proposed rule but indicated that it would provide that information prior to the start of the Model.

ASTRO expressed concern regarding this additional reporting requirement particularly given that so little information was shared in the proposed rule regarding the specific criteria. Additionally, we were concerned that the addition of new reporting requirements will require vendors to develop new software which will take time to develop and install, the cost of which will be borne by the radiation oncology practice. ASTRO recommended a delay in the implementation of the clinical data collection requirement to allow for a collaborative effort between ASTRO, vendors and CMS officials to establish a well thought out approach that would lessen the burden on practices.

In the final rule, CMS finalized the proposal to collect CDEs as previously described. The Agency did not provide specifics regarding the types of clinical data elements to be collected. However, it did release a Request for Information (RFI) that proposes draft CDEs for each of the specific disease sites (prostate, breast, lung, bone mets and brain mets) for public comment. CMS is seeking comments on the proposed CDEs identified and how they may relate to the goal of eventually establishing outcomes measures and informing pricing and monitoring, while at the same time minimizing collection burden. The deadline to submit comments on the proposed CDEs is October 19. According to the RFI, CMS is considering removal of CDEs for PY1 but will use stakeholder feedback to inform CDE collection standards that could be issued in advance of PY1 of the Model.

The table below includes the four RO Model quality measures and CAHPS® Cancer Care Survey, the level at which measures will be reported, and the measures' status as pay-for-reporting or pay-for-performance.

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
Advance 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	N/A

Proposed Calculation for the Aggregate Quality Score (AQS)

In the final rule, CMS establishes that quality measures will be scored as pay-for-performance or pay-for-reporting depending on whether established benchmarks exist. As previously described, the pay-for-performance measures for performance year 1 are 1) Advance Care Plan; 2) Preventative Care and

Screening: Screening for Depression and Follow-Up Plan; 3) Oncology: Medical and Radiation – Plan of Care for Pain. RO Model participants will 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 (>20 cases) for a given measure, that measure will be excluded from the AQS denominator calculation and the denominator would 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.

To calculate the AQS, CMS will sum each Professional participant's or Dual participant's points awarded for clinical data reporting (50 percent weight) with its aggregated points awarded for quality measures performance (50 percent weight) to reach a value that would range between 0 and 100 points. The AQS will be calculated 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 was supportive of the AQS scoring methodology but sought more information about the proposed benchmarks that the Agency plans to use for the RO Model and expressed concern about the eight-month calculation period, which delays payments to participating practices.

Additional Data Sharing Requirements

In addition to quality measures and clinical data elements data collection described above, CMS also proposed requiring RO participants to report on certain types of practice specific data. Information included the RO participant's TIN, in the case of freestanding centers and PGPs, or CCN in the case of a HOPD. Other proposed requirements included confirmation of NPIs for the physicians who bill radiation therapy services using the applicable TINs. Additionally, CMS proposed requiring RO participants to report on the number of Medicare and non-Medicare patients treated with radiation therapy during their participation in the model.

Additionally, CMS proposed asking RO participants 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 questioned 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 urged the Agency to refrain from requiring any additional data collection other than confirming NPIs, TINs and CCNs that are participating in the model.

In the final rule, CMS is modifying the proposed language to make the reporting of administrative data related to the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status optional for RO participants. According to the Agency, the data collected will be used to better understand participant's office activities, benchmarks, and to track participant compliance with RO Model requirements. The Agency recognizes concerns regarding the transmission of proprietary

information and notes that it will handle the data in accordance with applicable laws, including but not limited to Freedom of Information Act (FOIA).

Certified Electronic Health Records Technology (CEHRT)

To be an Advanced APM, the RO Model must meet the criteria specified in MACRA, which requires participants to use CEHRT. 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 the 2015 Base Edition CEHRT throughout the model year within 30 days of the start of the first performance year.

Patient Safety Organizations

The Agency also proposed that each Technical and Dual participant annually attest to active participation in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). ASTRO was pleased that the Agency modified the language in the final rule to ensure that RO Model participants who are also RO-ILS: Radiation Oncology Incident Learning System® (RO-ILS) participants are able to leverage this participation to comply with the PSO requirement. In addition, ASTRO recommended 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.

In the final rule, CMS finalized the PSO participation requirement. However, the requirement was modified so that practices may participate in any PSO, rather than specifically a radiation oncology-specific PSO. According to the Agency, this alleviates concerns regarding additional fees that may be required to participate in a radiation oncology specific PSO (RO-ILS does not charge a participation fee). RO participants have until the attestation period near the end of PY1 to initiate participation with a PSO.

Monitoring

In the proposed rule, CMS proposed to monitor RO participants for compliance with Model requirements, including attempts to manipulate the system through patient recruitment and billing practices by focusing on patient and provider/supplier characteristics, such as variations in size, profit status, and episode utilization patterns, over time to detect changes that may suggest attempts at such manipulation. To monitor for these types of changes the Agency proposed the following medical record documentation requirements:

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

2) adhere to nationally recognized, evidence-based treatment guidelines when appropriate in treating Medicare beneficiaries or document in the Medical record the rationale for the departure from these guidelines;
3) assess the Medicare beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnosis;
4) assess the Medicare beneficiaries' performance status as a quantitative measure determined by the physician;
5) send a treatment summary to each Medicare beneficiary's referring physician within three months of the end of treatment to coordinate care;
6) discuss with each Medicare beneficiary prior to treatment delivery his or her inclusion in and cost-sharing responsibilities; and
7) perform and document Peer Review for 50 percent of new patients in performance year 1, 55 percent of new patients in performance year 2, 60 percent of new patients in performance year 3, 65 percent of patients in performance year 4, and 70 percent of patients in performance year 5, preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within two weeks of starting treatment.

ASTRO expressed concern that these monitoring requirements established another layer of reporting burden on participating practices. Additionally, we requested clarification regarding how CMS would collect this data given that much of it is not collected in existing EHR systems. Furthermore, ASTRO recommended that the monitoring requirements be replaced by establishing an accreditation requirement that ensures practices are adhering to quality standards, including the delivery of safe care and have the systems, personnel, policies and procedures, validated by an external surveyor.

CMS finalized the monitoring requirements as proposed. The Agency did acknowledge that accreditation by a nationally recognized organization, such as ASTRO, can serve as an indicator of the overall quality of care provided by an RT provider or RT supplier. However, the Agency does not believe that accreditation provides a full picture of quality care delivery in radiation oncology. While CMS is not using accreditation status as a proxy for quality, the Agency may use an optional web-based survey to gather data from participants on administrative data points, including their accreditation status, indicating the importance of this information to understanding participants' activities associated with ensuring the delivery of quality care and overall patient safety.

Performance Feedback

In the proposed rule, CMS proposed using clinical data, quality measures reports, claims data and compliance monitoring to provide information to RO participants on their adherence to evidence-based practice guidelines, quality and patient experience measures, and other quality initiatives. ASTRO requested clarification and input on the frequency and design of these reports. 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. The Agency finalized this proposal with no modifications.

Annual Reconciliation and True Up Process

In the proposed rule, CMS proposed to establish an annual reconciliation process that would begin in August after the end of the performance period. A true-up of the reconciliation would take place one year later. According to the Agency, the delayed timing for the reconciliation period allows time for claims run-out, data collection, reporting and the calculation of 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. The subsequent true up of the reconciliation involves the calculation of additional payments or repayments for incomplete episodes and duplicate radiation therapy services that are identified after the claims run out period has closed.

ASTRO expressed concern that the combined reconciliation and true up process would create a 20-month lag between the end of the performance period and the time in which payment adjustments would be made, restricting cash flow and putting participating practices in financial jeopardy. ASTRO urged the Agency to develop a more expeditious process that would ensure financial stability for participating practices. CMS finalized the reconciliation process with a modification indicating that the reconciliation period will begin "as early as August", indicating that the initial reconciliation period may not begin until later in the year following the end of the performance period.

Additionally, CMS finalized the reconciliation payment methodology as proposed. To calculate the reconciliation payment, CMS will sum all of the money the RO participant owes CMS due to incomplete episodes and duplicate services and subtract the amount from the incorrect payment withhold amount. This excludes any outstanding amounts owed by the Medicare FFS beneficiary.

For Professional participants, CMS will add the incomplete episode amount to the quality reconciliation amount, which is determined by multiplying the participant's AQS against the 2-percentage point maximum withhold amount.

For Technical participants, in performance years 1 and 2, the reconciliation amount would be equal to the incomplete episode reconciliation amount. There would be no further additions or subtractions. For Technical participants in performance years 3, 4, and 5, the incomplete episode reconciliation amount would be added to the patient experience reconciliation amount. Technical and Dual participants can potentially earn up to the full amount (1 percent of technical episode payment amounts) of the patient experience withhold for a given performance year based on results from the patient-reported CAHPS Cancer Care Radiation Therapy Survey.

For Dual participants, in performance years 3, 4, and 5, CMS will add the incorrect payment reconciliation amount to the quality reconciliation amount. As described above, the quality reconciliation amount is determined by multiplying the participant's AQS against the total two-percentage point maximum withhold amount.

The geographic adjustment and the 2 percent sequestration adjustment will be applied to the incorrect payment withhold, quality withhold, and patient experience withholds during the reconciliation process.

Timely Error Notice and Reconsideration Request Process

CMS finalized a timely error notice and reconsideration request period in which RO participants may dispute suspected errors in the calculation of their reconciliation report. The dispute process is limited to the reconciliation process and will not be extended to RO Model pricing methodology or AQS methodology. The Agency establishes 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 45 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. A CMS reconsideration official will issue a written determination within 60 days after the submission of review materials.

In the proposed rule, the Agency proposed a 30-day timely error notification period. ASTRO expressed concern that 30-day review and notification timeline was too short. Based on ASTRO's concerns the Agency extended the review and notification timeline to 45-days in the final rule.

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[2]. The Agency establishes that the RO participant, specifically either a Professional participant or a Dual participant, will be the APM entity. 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.

In the proposed rule, the Agency projected that 82 percent of RO participants will receive the APM incentive payment for at least one performance period during the model performance period. Additionally, CMS stated that it would issue an "individual practitioner list" for Professional participants and Dual participants to review, revise, certify and return to CMS so that the Agency may make Qualified APM Participant (QP) determinations for the Advanced APM incentive payment amount and to identify any MIPS eligible clinicians who would be scored for MIPS based on their participation in the RO Model as a MIPS APM.

ASTRO expressed concern that 18 percent of model participants would be deemed MIPS APMS despite being compelled to participate in the RO Model. To make the argument that CMS should designate all RO Model participants as QPs, ASTRO cited two key factors that ensure practices meet the Advanced APM criteria:

<u>Capitated Payment Arrangement</u>

[2] 84 Fed. Reg. 34514 ("[W]e intend for the RO Model to qualify as an Advanced APM, and also meet the criteria to be a MIPS APM.")

One way of meeting the financial risk standard is through capitated arrangement. *See* 42 C.F.R. § 414.1415(c)(6) ("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.")

Qualified APM Participant Thresholds

To qualify as a QP, a provider must meet certain thresholds that are set to increase through 2023.[3] In 2021, the provider must receive at least 50 percent of their Medicare Part B payments or see at least 40 percent of Medicare patients through an Advanced APM entity. ASTRO believes that providers who are mandated to participate in the RO Model will necessarily meet these increasing thresholds as a result of two characteristics of the proposed model: first, the proposed model mandates participation from selected providers, and second, the proposed model is intended by CMS to be, and is, an Advanced APM (whether considered a capitated arrangement or otherwise).

Given these two characteristics of the model, most, if not all, of the RO participants' Medicare patients will be seen through an Advanced APM entity. Thus, the RO participants will necessarily satisfy the requirements to be a QP and therefore be eligible to receive the APM Incentive Payment.

In the final rule, CMS stated that it continues to believe that most RO Model participants will meet the Qualified APM Participant (QP) criteria. However, the Agency did not acknowledge ASTRO's assertion that all RO Participants be designated as Qualified Advanced APM Participants due to the Model's capitated payment arrangement.

Medicare Program Waivers

Technical Component Waiver

In the proposed rule, CMS proposed a waiver of the MACRA-required Technical Component Payments in the calculation of the APM incentive payment for freestanding facilities. 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 asserted in the proposed rule 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

[3] 42 C.F.R. § 414.1430. *See also* CMS, Advanced Alternative Payment Models (APMS), https://qpp.cms.gov/apms/advanced-apms?py=2019.

services in hospital outpatient settings would not have those services included in the calculation of the APM incentive payment. The Agency 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 disagreed with this assertion, stating that it was particularly egregious given the proposed 5 percent discount on technical component payments. Furthermore, the technical component for radiation therapy services includes the fixed costs associated with practice expenses for the equipment and personnel 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 asserted that there was 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 finalized the technical component waiver and failed to provide a justification for its decision to eliminate the APM incentive payment that meets the APA's legal threshold for regulatory actions. This is particularly disappointing given that CMS proposes to mandate participation *and* then waives 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. ASTRO remains concerned that that this regulatory action conflicted with the spirit and letter of MACRA and is further evidence that RO model is a payment cut disguised as a test.

<u>MIPS Payment Adjustment Waiver</u>

In the proposed rule, CMS proposed 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. ASTRO was disappointed with this proposal, particularly given the amount of time and resources

that these MIPS Eligible Clinicians put into participating in the MIPS program. ASTRO strongly urged 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.

In the final rule, based on ASTRO's concerns, CMS did not finalize its proposal to waive the MIPS payment Adjustment factors for the PC of RO Model payments. The Agency recognizes the concerns expressed in the proposed rule and does not want to create a general disincentive for participating in Advanced APMs by waiving MIPS adjustments that may positively impact RO participants' payments.

Evaluation

In the final rule, CMS states that it will focus evaluation efforts on understanding how successful the RO Model is in achieving improved quality and reduced expenditures, as evidenced by changes in radiation therapy utilization patterns, costs for Medicare FFS beneficiaries, changes in utilization and costs with other services that may be affected as a result of the RO Model (such as ED services, imaging, prescription drugs, and inpatient hospital care), performance on clinical care process measures (such as adhering to evidence-based guidelines), patient experience of care, and provider experience of care. The evaluation will use a multi-level approach, including analyses at the CBSA-level, participant-level and beneficiary-level.

Potential Overlap with other Models

CMS believes that the RO Model is compatible with other CMS models and programs. However, the Agency recognizes that there may be situations in which overlap may occur at the beneficiary level in which a beneficiary in the RO Model may be receiving care associated with another payment model, as well as at the provider and supplier level in which a physician or organization could be participating in multiple models. Below are current scenarios for potential overlap.

<u>Accountable Care Organizations (ACO)</u>

According to CMS, there would be potential for overlap between the RO Model and ACO initiatives, but because the RO Model is an episode-based payment initiative, providers and suppliers participating in the RO Model would not be precluded from also participating in an ACO initiative. CMS believes that shared savings payments under an ACO initiative have the potential to overlap with discounts and withholds in the RO Model; however, the agency said it is difficult to determine the level of potential overlap. The Agency proposes to continue reviewing potential overlap in these situations and pursue any future changes through ACO initiative procedures.

<u>Oncology Care Model (OCM)</u>

Because the OCM and RO Model both involve care for patients with a cancer diagnosis who receive radiation therapy services, CMS anticipates that 30 percent of OCM practices that provide RT services will participate in the RO Model. The OCM is a total cost of care model that encompasses a six-month episode of care. OCM episodes that include radiation therapy services 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 in which 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.

Bundled Payments for Care Improvement (BPCI) Advanced

While there are no cancer episodes included in the design of BPCI Advanced, a Medicare beneficiary in a RO episode could be treated by a provider or suppler that is participating in BPCI Advanced. Since prospective episode payments made under the RO Model will not be affected by BPCI Advanced, BPCI Advanced will determine whether to account for RO Model overlap in its reconciliation calculations.

In the final rule, CMS did not make any modifications to address issues or concerns related to model overlap. The Agency propose overlap policies for the RO Model through future public notice and comment rulemaking.

Additional Resources

Additional information about the RO Model final rule can be found at the following links:

Final rule language: https://innovation.cms.gov/media/document/specialty-care-models-rule

CMS Fact Sheet: https://www.cms.gov/newsroom/fact-sheets/radiation-oncology-ro-model-fact-sheet

RO Model Description and Technical Documents: https://innovation.cms.gov/innovation-models/radiation-oncology-model