ASTRO
TARGETING CANCER CARE

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

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

2022 RO Model Proposed Rule Summary

On July 19, 2021, the Centers for Medicare and Medicaid Services released modifications to the Radiation Oncology Model (RO Model) as part of the 2022 Hospital Outpatient Prospective Payment System (HOPPS) proposed rule. The proposed changes to the RO Model include slight revisions to the discount factor; the exclusion of brachytherapy from the list of included modalities and liver cancer from the list of cancer types; modification to the application of Advanced Alternative Payment Model (APM) status through the implementation of a multi-track classification construct; and the establishment of an Extreme and Uncontrollable Circumstances (EUC) policy.

The concerns of the radiation oncology community have been largely ignored in this proposed rule. ASTRO is extremely disappointed, particularly given the amount of time and resources that have been devoted to the development of an alternative payment model that meets the needs of both the physician and patient. ASTRO believes the proposal rule seriously jeopardizes access to radiation therapy for patients served by practices forced to participate in the model. ASTRO is calling upon President Biden and Congress to immediately intervene on the flawed RO model, as well as draconian cuts proposed in the Medicare Physician Fee Schedule.

Savings Target

In the 2022 HOPPS proposed rule, the RO Model remains a mandatory model encompassing 30 percent of all RT episodes, which includes 950 physician group practices (PGPs), hospital outpatient departments, and freestanding radiation therapy centers across preselected Core Based Statistical Areas (CBSA). CMS anticipates that the RO Model will include approximately 282,000 episodes involving 250,000 Medicare FFS beneficiaries, equating to $4.6 billion in total episode spending in allowed charges over the five-year duration of the program (2022-2026). This total episode spending is about $700 million less than CMS anticipated for the five years (2021-2025) in the final rule published in September 2020. CMS estimates that, on net, the Medicare program will save $160 million over the model performance period.

ESTIMATES OF MEDICARE PROGRAM SAVINGS (MILLIONS $) FOR RADIATION ONCOLOGY MODEL						
	Year of Model					
	2022	2023	2024	2025	2026	Total*
Net Impact to Medicare Program Spending	$ (20)	$ (30)	$ (20)	$ (40)	$ (40)	$ (160)
Change to Incurred FFS Spending	$ (20)	$ (20)	$ (30)	$ (30)	$ (30)	$ (130)
Changes to MA Capitation Payments	$ (10)	$ (20)	$ (20)	$ (20)	$ (30)	$ (100)
Part B Premium Revenue Offset	$ 10	$ 10	$ 10	$ 10	$ 10	$ 60
Total APM Incentive Payments	$ -	$ -	$ 10	$ -	$ -	$ 10
Episode Allowed Charges	$ 830	$ 870	$ 910	$ 960	$ 1,000	$ 4,580
Episode Medicare Payment	$ 650	$ 680	$ 710	$ 750	$ 780	$ 3,570
Total Number of Episodes	53,300	54,900	56,400	58,000	59,600	282,200
Total Number of Beneficiaries	51,900	53,500	54,900	56,500	58,100	250,200
*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.						

Based on proposed modifications to the design of the RO Model, CMS estimates that on average, Medicare FFS payments to Physician Group Practices (PGPs) will increase by 5.5 percent and Medicare FFS payments to Hospital Outpatient Departments (HOPDs) will decrease by 9.6 percent over the duration of the model demonstration period. ASTRO believes the increase in PGPs payments is

deceiving, as it is likely relative to significant reductions expected in Medicare physician fee schedule payments as proposed by CMS. The table below demonstrates estimated impact by year:

Radiation Oncology Model PGP vs. HOPD Allowed Charges Impacts 2022-2026						
% Impact	**2022**	**2023**	**2024**	**2025**	**2026**	**2022-2026**
PGP	1.8%	3.5%	5.2%	6.8%	8.5%	5.5%
HOPD	-7.2%	-8.3%	-9.3%	-10.4%	-11.3%	-9.6%

Discount Factor

In the 2020 Specialty Care Model final rule, CMS finalized the discount factor for the RO Model at 3.75 percent off the Professional Component (PC) payment and 4.75 percent off the Technical Component (TC) payment. Due to proposals to remove brachytherapy as an included service and liver cancer as an included cancer type, which are further discussed in subsequent pages, the Agency is proposing to reduce the discount factor on the PC and the TC by 0.25 percent, respectively.

According to the Agency, the removal of these two components of the RO Model, enables it to lower the discount factor to 3.50 percent off the PC payment and 4.50 percent off the TC payment without increasing the size of the RO Model, i.e. requiring more practices to participate in the mandatory demonstration.

CMS anticipates that based on this proposal it will be able to save 3.2 percent in Medicare FFS spending. The Agency states that if the proposals to remove brachytherapy and liver cancer from the RO Model are not finalized, the reduced discount factors will also not be finalized.

ASTRO remains concerned that discount factors of this magnitude will put many practices in financial jeopardy. We continue to believe that a discount factor of 3 percent or less is more appropriate and would allow participating practices the opportunity to successfully participate in the model with limited financial risk.

Furthermore, CMS has done nothing to address concerns that the RO Model's payment methodology has the potential to significantly harm those practices that are already operating very efficiently or those that serve rural or socioeconomically disadvantaged populations requiring greater resource expenditures. These practices, operating on thin margins, could be forced to take drastic steps to continue serving patients.

Finally, CMS has yet to address concerns regarding the significant investments required to operate radiation oncology clinics. The discount factor and the punitive payment methodology do not recognize the significant investment in capital equipment necessary to operate a clinic. This runs counter to the Biden Administration's goal of "Ending Cancer as We Know It," as practices will struggle to invest in the human and technological infrastructure to provide high quality, state-of-the-art care.

Performance Period

CMS initially established a five-year performance period for the RO Model, beginning January 1, 2021, and concluding on December 31, 2025. In the 2021 HOPPS final rule, CMS shortened the performance period by six months, July 1, 2021 through December 31, 2025. Due to the passage of the ASTRO-supported COVID-19 Emergency Relief Act, the RO Model implementation date was delayed until no earlier than January 1, 2022.

In the 2022 HOPPS proposed rule, CMS is proposing to modify the duration of the RO Model to begin January 1, 2022 and conclude on December 31, 2026. If the RO Model is prohibited by law from starting on January 1, 2022, the model would begin on the earliest date permitted by law, i.e., January 1, April 1, or July 1. Each performance year (PY) will be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period. If the model performance period begins on a date other than January 1, the PY would begin on that date and end on December 31 of the same year.

RO Model Participant Exclusions

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

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

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

<u>Low Volume Opt-Out</u>

In the 2020 RO Model final rule, CMS established a low volume opt-out for practices with fewer than 20 RT episodes across all CBSAs selected for participation in the Model. The most recent year with claims data available will be used to determine the eligibility for the low volume opt-out. At least 30 days prior to the start of each PY, CMS will notify RO participants of their eligibility for the low volume opt-out. Participants interested in opting-out must attest to do so prior to the start of the next PY.

CMS clarifies in the 2022 HOPPS proposed rule, that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine eligibility for subsequent PYs. Additionally, the Agency is proposing that an entity would not be eligible for the low volume opt-out if its legacy TIN or legacy CMS Certification Number (CCN) was used to bill Medicare for 20 or more episodes in the two years prior to the applicable PY across all CBSAs selected for participation in the RO Model.

CMS proposes that legacy CCN means a CCN that a RO participant that is a hospital outpatient department, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for included RT services. A legacy TIN means a TIN that a RO participant that is a PGP, or a freestanding radiation therapy center, or its predecessor(s), previously used to bill Medicare for included RT services but no longer uses to bill Medicare for RT services. The Agency is

proposing to remove any incentive for RO participants to change their TIN or CCN to become eligible for the low volume opt-out.

Cancer Types

In the 2020 Specialty Care Models final rule, CMS finalized 16 cancer types (Anal Cancer, Bladder Cancer, Bone Metastases, Brain Metastases, Breast Cancer, Cervical Cancer, Central Nervous System (CNS) Tumors, Colorectal Cancer, Head and Neck Cancer, Liver Cancer, Lung Cancer, Lymphoma, Pancreatic Cancer, Prostate Cancer, Upper Gastrointestinal (GI) Cancer, and Uterine Cancer) for inclusion in the RO Model.

In the 2022 HOPPS proposed rule, CMS is proposing to remove liver cancer from the list of cancer types included in the RO Model. According to the Agency, treatment of liver cancer with RT services continues to develop, with limited guidance for first line use of radiotherapy. Therefore, liver cancer does not meet the inclusion criteria (as described below) because it is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines. Below is a chart detailing the updated list of included ICD-10 codes.

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
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

In the 2020 RO Model final rule, CMS finalized the inclusion of 16 different disease types for inclusion in the RO Model. Cancer type inclusion required that the cancer type be commonly treated with radiation and associated with current ICD-10 codes that have demonstrated pricing stability. CMS also set forth that it will remove cancer types from the RO Model if it determines that RT is no longer appropriate to treat that cancer type per nationally recognized, evidence-based clinical treatment guidelines; CMS

discovers a greater than or equal to 10% error in the established national base rates; or the Secretary determines that the cancer type is not suitable for inclusion in the RO Model.

In the 2022 HOPPS proposed rule, CMS is proposing to amend these requirements such that to be included in the RO Model, a cancer type must be commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines; associated with current ICD-10 codes that have demonstrated pricing stability, which is determined by analyzing the interquartile ranges of the episode prices across cancer types as described in the Specialty Care Models final rule; and the Secretary must not have determined that the cancer type is not suitable for inclusion in the RO Model.

Removal of Brachytherapy from Included RT Services

In the 2019 Specialty Care Models proposed rule, CMS proposed to include all RT services, i.e. external beam radiation therapy (3-D Conventional, IMRT, IGRT, SRS, SBRT and Protons) along with brachytherapy and IORT as included RT services in the RO Model.

In the 2020 Specialty Care Models final rule, CMS determined that IORT should be excluded from the list of included RT services due to its limitation to certain disease sites. In the 2022 HOPPS proposed rule, CMS reaffirms its decision to omit IORT from the RO Model despite stakeholder requests that it be included. According to the proposed rule, CMS notes that in addition to the limited use of IORT, it is also not a site neutral modality. The Technical Component of IORT is primarily delivered in HOPDs during surgery instead of in freestanding radiation therapy centers. This does not align with the Agency's goal of testing site neutral payments for services that can be delivered in either HOPDs or freestanding radiation therapy centers. CMS is seeking comment on whether and how it might include IORT in the RO Model pricing methodology in future years.

Additionally, CMS is proposing to remove brachytherapy from the list of RT services included in the RO Model. Stakeholders, including ASTRO, expressed concern that the RO Model undervalued the use of brachytherapy particularly in situations involving multi-modality care. There was also great concern that the model did not accurately recognize shifts in patient care between physicians and sites of service as brachytherapy is typically delivered in large hospital settings or regional cancer centers. According to the proposed rule, CMS does not seek to either incentivize nor discourage the use of one modality of treatment over another. CMS recognizes that brachytherapy is a high-value RT service, which warrants inclusion in the RO Model; however, given these concerns, the Agency is proposing to remove it as an included modality.

Furthermore, CMS states that it will continue to monitor utilization of brachytherapy, both as single modality and multimodality among RO participants compared to non-participants and consider whether there is opportunity to adjust pricing for multimodality episodes, without disrupting the RO Model design, and potentially add brachytherapy to the RO Model in the future. The Agency is seeking comments on how multimodality care, particularly that involve brachytherapy, may be handled in the future.

The Agency's proposal to remove brachytherapy from the RO Model, modifies the RO Model HCPCS code list that is associated with RO Model episodes of care. Below is a revised HCPCS Code list based on this proposal:

LIST OF RO MODEL BUNDLED HCPCS			
HCPCS	**HCPCS Description**	**HCPCS**	**HCPCS Description**
77014	CT guidance for placement of	77412	Radiation treatment delivery
77021	MRI guidance for needle placement	77417	Radiology port images(s)
77261	Radiation therapy planning	77427	Radiation tx management x5
77262	Radiation therapy planning	77431	Radiation therapy management
77263	Radiation therapy planning	77432	Stereotactic radiation trmt
77280	Set radiation therapy field	77435	SBRT management
77285	Set radiation therapy field	77470	Special radiation treatment
77290	Set radiation therapy field	77499	Radiation therapy management
77293	Respirator motion mgmt simul	77520	Proton trmt simple w/o comp
77295	3-d radiotherapy plan	77522	Proton trmt simple w/comp
77299	Radiation therapy planning	77523	Proton trmt intermediate
77300	Radiation therapy dose plan	77525	Proton treatment complex
77301	Radiotherapy dose plan IMRT	G0339	Robot lin-radsurg com, first
77306	Telethx isodose plan simple	G0340	Robot lin-radsurg fractx 2-5
77307	Telethx isodose plan cplx	G6001	Echo guidance radiotherapy
77321	Special teletx port plan	G6002	Stereoscopic x-ray guidance
77331	Special radiation dosimetry	G6003	Radiation treatment delivery
77332	Radiation treatment aid(s)	G6004	Radiation treatment delivery
77333	Radiation treatment aid(s)	G6005	Radiation treatment delivery
77334	Radiation treatment aid(s)	G6006	Radiation treatment delivery
77336	Radiation physics consult	G6007	Radiation treatment delivery
77338	Design mlc device for IMRT	G6008	Radiation treatment delivery
77370	Radiation physics consult	G6009	Radiation treatment delivery
77371	SRS multisource	G6010	Radiation treatment delivery
77372	SRS linear based	G6011	Radiation treatment delivery
77373	SBRT delivery	G6012	Radiation treatment delivery
77385	IMRT dlvr smpl	G6013	Radiation treatment delivery
77386	IMRT dlvr cplx	G6014	Radiation treatment delivery
77399	External radiation dosimetry	G6015	Radiation tx delivery imrt
77402	Radiation treatment delivery	G6016	Delivery comp IMRT
77407	Radiation treatment delivery	G6017	Intrafraction track motion

Secondary Diagnosis

In the 2020 Specialty Care Models final rule, CMS provided guidance 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. The following clarification was provided that establishes how cancer types are assigned to an episode based on frequency of claims:

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.

Since the publication of the Specialty Care Models final rule, stakeholders have sought clarification on how to identify when there are fewer than two claim lines for brain metastases, bone metastases or other secondary malignancies. CMS clarifies in this proposed rule that if there are not at least two claim lines for brain metastases or at least two claim lines for bone metastases or at least two claim lines for any other secondary malignancy, then the Agency will assign the episode the cancer type with the highest line count among all other cancer types.

Payment Methodology Modifications

Baseline Period

CMS is proposing to add a definition for "baseline period", which specifies which episodes (dependent on the model performance period) are used in the pricing methodology. "Baseline period" is defined to mean the three calendar year period that begins on January 1 no fewer than five years but no more than six years prior to the start of the model performance period, during which episodes must initiate in order to be used in the calculation of the National Base Rates, participant-specific professional and technical historical experience adjustments for the model performance period, and the participant-specific professional and technical case mix adjustments for PY1. The baseline period is proposed to be January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in 2022, in which case the base line period would be adjusted according to the new model performance period. The chart below details how the change in the baseline period influences the overall model payment methodology:

DATA SOURCES AND TIME PERIODS USED TO DETERMINE VALUES OF THE RO MODEL'S KEY PRICING COMPONENTS						
Key Components	**Data Source**	**PY1 (2022)**	**PY2 (2023)**	**PY3 (2024)**	**PY4 (2025)**	**PY5 (2026)**
National Base Rates	HOPD Episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Trend Factor	Non-participant episodes	(2019 volume*2022 rates)/(2019 volume*2019 rates)	(2020 volume*2023 rates)/(2019 volume*2019 rates)	(2021 volume*2024 rates)/(2019 volume*2019 rates)	(2022 volume*2025 rates)/(2019 volume*2019 rates)	(2023 volume*2026 rates)/(2019 volume*2019 rates)
Winsorization Thresholds	HOPD Episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Case Mix Coefficients	HOPD Episodes	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Case Mix Values [and whether eligible (>60 episodes) to receive case mix adjustment]	Participant Specfic	2017-2019	2018-2020	2019-2021	2020-2022	2021-2023
Historical Experience Adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant Specfic	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
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) 2019	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) 2019	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2019	WORK/PE/MP Shares PC (66/30/4) TC(0/99/1) 2019
Low Volume Opt-Out Eligibility (<20 episodes)	Participant Specfic	2020	2021	2022	2023	2024

Episode Attribution

In the 2020 Specialty Care Models final rule, CMS finalized that episodes would be excluded from the National Base Rate calculation that are not attributed to an RT provider or RT supplier. Additionally, episodes were excluded if either the PC or TC is attributed to an RT provider or RT supplier with a US Territory service location or to a PPS-exempt entity, but that services within an episode provided in a US Territory or provided by a PPS-exempt entity would be included in episode pricing. CMS excluded all episodes furnished by a CAH, as well as claims data associated with services delivered in Maryland, Vermont, at an inpatient facility or ASC.

In the 2022 HOPPS proposed rule, CMS is proposing to simplify episode construction, attribution, and pricing. This entails excluding all Maryland, Vermont, and US Territory claims, and all CAH, inpatient, ASC and PPS-exempt claims in the same manner before episodes are constructed and attributed to a RT provider or RT suppler. Furthermore, the Agency is proposing to exclude all claims of an HOPD participating in PARHM, as well as episodes that are attributed to an RT provider or RT supplier that is located in a ZIP Code not assigned to a CBSA for model participation.

National Base Rates

In the 2020 Specialty Care Models final rule, CMS finalized its use of Medicare FFS claims in the calculation of episode payment using a weighted methodology that would weight the most recent observations more heavily than those that occurred in earlier years. In the final rule, CMS weighted 2016 data at 20 percent, 2017 data at 30 percent and 2018 data at 50 percent.

In the 2022 HOPPS proposed rule, CMS is proposing to update its approach to this methodology. The Agency is removing references to specific calendar years; however, it is still constructing episodes based on dates of service for Medicare FFS claims paid during the baseline period, as well as claims that are included under an episode where the initial treatment planning service occurred during the baseline period. Additionally, the more recent observations will be weighed more heavily than those that occurred in earlier years. Therefore, the Agency will continue to weigh episodes that initiated in the first year of the baseline period at 20 percent, episodes that initiated in the second year of the baseline at 30 percent, and episodes that initiated in the third year of the baseline period at 50 percent. The Agency seeks comment on this proposed change.

CMS has modified the National Base Rates based on the proposed revised baseline period, as well as the proposal to remove brachytherapy from the list of included modalities and liver from the list of cancer types included in the RO Model. Below is a comparison of the National Base Rates finalized in the 2020 Specialty Models final rule and the proposed rates set for 2022.

NATIONAL BASE RATES						
CANCER_TYPE	2021 PC	2022 PC	% Change	2021 TC	2022 TC	% Change
Anal Cancer	$3,001	$3,104	3%	$ 16,544	$ 16,801	2%
Bladder Cancer	$2,688	$2,787	4%	$ 13,292	$ 13,556	2%
Bone Metastases	$1,398	$1,446	3%	$ 5,972	$ 6,194	4%
Brain Metastases	$1,602	$1,652	3%	$ 9,649	$ 9,879	2%
Breast Cancer	$2,081	$2,060	-1%	$ 10,129	$ 10,002	-1%
CNS Tumor	$2,511	$2,558	2%	$ 14,711	$ 14,762	0%
Cervical Cancer	$3,829	$3,037	-21%	$ 17,581	$ 13,560	-23%
Colorectal Cancer	$2,449	$2,508	2%	$ 12,040	$ 12,201	1%
Head and Neck Cancer	$3,019	$3,108	3%	$ 17,485	$ 17,497	0%
Liver Cancer	$2,082	$ -	$ -	$ 11,976	$ -	$ -
Lung Cancer	$2,181	$2,231	2%	$ 11,994	$ 12,142	1%
Lymphoma	$1,690	$1,724	2%	$ 7,855	$ 7,951	1%
Pancreatic Cancer	$2,394	$2,481	4%	$ 13,384	$ 13,637	2%
Prostate Cancer	$3,260	$3,378	4%	$ 20,249	$ 20,416	1%
Upper GI Cancer	$2,586	$2,667	3%	$ 13,530	$ 14,623	8%
Uterine Cancer	$2,436	$2,737	12%	$ 11,869	$ 14,156	19%

Trend Factor

The Trend Factor 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.

In the 2022 HOPPS proposed rule, CMS is proposing to modify the trend factor numerator so that it is the product of (a) the component's FFS payment rate (as paid under HOPPS or MPFS) for the calendar year (CY) of the upcoming PY and (b) the average number of times each HCPCS code (relevant to the

component and the cancer type for which the trend factor will be applied) was furnished three years prior to the CY used to determine the FFS payment. The denominator is proposed to be the product of (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applied) was furnished in the most recent year of the baseline period and (b) the corresponding FFS payment rate for the most recent year of the baseline period. The proposed trend factor calculation for PY 1 (2022) follows:

$$\text{2022 Trend Factor} = \frac{\text{(2019 volume * 2022 corresponding FFS rates paid under HOPPS or MPFS)}}{\text{(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS)}}$$

For those services that receive contractor pricing, CMS will calculate the average paid amounts each year in the baseline period for each of these RT services, using the most recent CY with claims data available, to determine their average paid amount that would be used in the calculations of the national base rates.

CMS will make the trended national base rates available on the RO Model website prior to the start of the applicable PY, after CMS has issued the annual HOPPS and MPFS final rules. This means practices will likely have less than two months to understand their payment rates for the coming PY, which is inadequate for practices to understand the model's impact.

CMS is seeking comment on the years used in the trend factor's numerator and denominator calculation.

Geographic Adjustment

In the 2020 Specialty Care Models final rule, CMS established the Geographic Adjustment by which RO Model specific RVU values were derived from the National Base Rates, which were based on the 2016-2018 base period. These RVU shares are part of the calculation that determines the RO Model specific RVU values. In the 2021 HOPPS proposed rule, CMS is modifying the base line period to 2017-2019, and using 2019 data to calculate the implied RVU shares as described in the chart below. CMS welcomes comments on this proposed modification.

RVU Shares					
Professional Component			Technical Component		
WORK	PE	MP	WORK	PE	MP
0.65	0.31	0.04	0	0.99	0.01

Quality Withholds

After removing the Quality Withholds in the 2021 HOPPS final rule, CMS is proposing to reinstate the Quality Withhold set at 2 percent of the PC beginning January 1, 2022 (PY1). The 2 percent withhold would be applied to the trended national base rates after case mix and historical experience adjustments.

Sequestration

In the 2020 Specialty Models final rule, CMS finalized the application of a 2 percent deduction from the RO Model payment methodology for sequestration. In the 2022 HOPPS proposed rule, CMS recognizes

that at times the requirements for sequestration are modified by legislation or regulation. Therefore, the Agency is modifying the RO Model payment methodology by removing the percentage amount associated with sequestration and indicating that sequestration will be applied in accordance with applicable law.

Data sources and Time Periods Used to Determine RO Model Payment Methodology Values

Very few changes were made to the payment methodology, other than the update to the baseline period and modest policy changes to specific components, such as the application of the sequester.

Quality Measures

In the 2021 HOPPS final rule, CMS delayed the RO Model quality measures requirements to PY 2. In this proposed rule, the Agency is proposing that Professional and Dual participants submit quality measures data starting with PY1 (January 1, 2022). Under this proposal, if the model performance year starts mid-year (July), the CY collection period would remain the same (January – December). According to the Agency, this would allow RO participants to use their MIPS data submission to meet RO Model requirements.

For PY 1, Professional participants and Dual participants would be required to submit data for three pay-for-performance measures: 1) Plan of Care for Pain; 2) Screening for Depression and Follow Up Plan; and 3) Advance Care Plan.

A fourth measure, Treatment Summary Communication – Radiation Oncology, will be established as a pay-for-reporting measure. Data collected will be used to propose a benchmark to re-specify it as a pay-for-performance measure in PY 3. CMS is proposing that it may update the specifications for this measure should new specifications from the measure's steward meet the RO Model's needs.

All data will be submitted via the RO Model secure data portal.

CAHPS Cancer Care Survey

In the 2020 Specialty Care Model final rule, CMS finalized that it would have a CMS-approved contractor administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Cancer Care Survey beginning in April 2021. Due to the change in the model performance period, CMS is proposing to begin administering the survey as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

Clinical Data Elements (CDE)

In the 2020 Specialty Care Model final rule, CMS finalized the collection of CDEs, not available on claims or captured in quality measures, on Medicare beneficiaries treated for prostate, breast, lung, bone metastases, and brain metastases. In the 2021 HOPPS final rule, CMS established that the CDE collection period would begin on January 1, 2022, with the first submission deadline for the January 1, 2022 through June 30, 2022 data collection period due in July 2022. At the time, this was six-months after the initial launch of the model, which at the time was expected to start July 1, 2021. In the 2022 HOPPS proposed rule, CMS retains the policy to implement the data collection period effective January 1, 2022, despite the subsequent delay in Model implementation. The Agency seeks comment on this proposal.

ASTRO remains concerned regarding the burden associated with quality measures reporting, particularly the reporting associated with the CDEs, which have not been identified and therfore are unlikely to be easily reported through seamless electronic submission.

Certified Electronic Health Records Technology (CEHRT)

In the Specialty Care Models final rule, CMS established that RO Model participants must use CEHRT and annually certify to its use during the model performance period within 30 days of the start of each PY. CMS affirms that policy in the 2022 HOPPS proposed rule and proposes that if an RO participant begins participation in the RO Model at any time during an ongoing PY, they must certify their use of CEHRT by the last determination snapshot date (August 31).

Reconciliation and True Up Process

In the 2022 HOPPS proposed rule, CMS retains its policy to initiate the annual reconciliation process in August after the end of the PY. 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.

In the 2020 Specialty Care Model final rule, CMS established that 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. In the 2022 HOPPS proposed rule, CMS is proposing to modify this policy for all incomplete episodes in such a way that will allow the Agency to reconcile the episode payment for the PC and TC that was paid to the RO participant(s) with what the FFS payments would have been for those RT services using no-pay claims. After reviewing incomplete episode data, CMS determined that the data did not support paying RO participants only the first installment of an episode for incomplete episodes, which was the previous policy.

This proposed change to the incomplete episode payment policy requires CMS to consider similar changes to the beneficiary coinsurance requirements associated with incomplete episodes. The Agency is proposing to modify the coinsurance associated with incomplete episodes so that it is set at 20 percent of the FFS amount applicable to the RT services provided.

Stop Loss Policy

In the 2020 Specialty Care Models final rule, CMS established a stop-loss limit of 20 percent for RO participants that have fewer than 60 episodes from 2016 through 2018 (the original baseline period) and were furnishing RT services at the time of the effective date of the Specialty Care Models Rule in selected RO Model CBSAs. Under the stop-loss limit, CMS would use no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the RO model and CMS would pay these RO participants retrospectively for losses in excess of 20

percent of what they would have been paid under FFS. Payments would be determined as part of the reconciliation process.

In the 2022 HOPPS proposed rule, CMS is proposing to modify this stop-loss limit policy so that it applies to RO participant that have fewer than 60 episodes during the proposed baseline period (2017-2019) and that were furnishing included RT services at any time before the start of the model performance period in CBSA's selected for participation in the RO Model. The Agency seeks comment on this modification.

Additionally, CMS is proposing to modify the definition of "stop-loss reconciliation amount" to mean the amount owed by CMS for the loss included under the Model to RO participants that have fewer than 60 episodes during the baseline period and were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

Application of Adjustments for HOPD or Freestanding Radiation Therapy Center with a Merger, Acquisition, or Other New Business Relationship, With a CCN or TIN Change

In the 2020 Specialty Care Models final rule, CMS finalized the requirement that entities must participate in the RO Model even if they have a new TIN or CCN as a result from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025, begins to furnish RT services within a CBSA selected for participation, and meets the RO Model's eligibility requirements. The Agency also finalized a requirement for advance notification regarding a new merger, acquisition, or other new clinical or business relationships so that the appropriate adjustments would be made to the new or existing RO participant's participant-specific professional episode payment and participant-specific technical episode payment amounts. Finally, CMS required that RO participants notify the Agency of any new clinical or business relationships that may or may not constitute a change in control. This would trigger a review of historical data to determine payment adjustments for the new or existing TIN or CCN.

In the 2022 HOPPS proposed rule, CMS is proposing to eliminate the requirement that RO participants provide a notification regarding all new clinical or business relationships that may or may not constitute a change in control. Rather the Agency believes that requiring RO participants to submit written notice of a change in TIN or CCN at least 90 days before the effective date of any change will capture the potential risk associated with new clinical or business relationships.

To address related payment adjustments, CMS is proposing to calculate in accordance with the RO participant's case mix adjustments based on all episodes and RO episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the three-year period that determines the case mix adjustment for each PY and all episodes and RO episodes, as applicable, attributed to the RO participant's current TIN or CCN during the three year period that determines the case mix adjustment for each PY. Similarly, the Agency is proposing to calculate the historical experience adjustments based on all episodes attributed to the legacy TIN or CCN during the baseline period and all episodes attributed to the RO participant's current TIN or CCN during the baseline period.

CMS seeks comments on the proposed changes to the case mix and historical experience adjustments are calculated for entities that have a change in TIN or CCN.

RO Model as an Advanced APM and MIPS-APM

In the 2022 HOPPS proposed rule, CMS reasserts that the RO Model meets the criteria of an Advanced APM, as well as a MIPS-APM. However, the Agency adjusts its estimate of the percentage of RO Model participants that are expected to achieve Advanced APM status from 82% of all participants to 80% of all participants.

The Agency also proposes to establish that those Professional and Dual participants who meet RO Model requirements, including use of CHERT, and who are eligible clinicians on a participation list, will fall into a category called "Track One" of the RO Model. The participation list is a list of RO Model participants that has been compiled by CMS, more detail is provided in subsequent paragraphs. CMS proposes to define "Track One" as an Advanced APM and MIPS APM track for Dual and Professional participants that use CEHRT. RO Model participants in Track One will be considered participating in the Advanced APM track of the RO Model, and CMS will make Qualifying APM Participant (QP) determinations for the eligible clinicians on the RO Model Participation List for Track one as provided in 414.1425. If eligible clinicians who are Track One participants do not meet the established QP thresholds, they will be considered MIPS-APM participants and can report to MIPS using reporting options applicable to MIPS APM participants.

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

Additionally, any failure to comply with the following monitoring requirements will result in Track Two status:

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.

CMS recognizes that an RO participant's noncompliance may not come to light until after CMS has treated the participant as if they were in Track One. In that event, the payments made based on QP status of the of the RO Participant would be constituted as overpayments. CMS considered removing the requirement that RO Model participants must meet all of the monitoring requirements to remain in Track One, but the Agency believes these requirements are important to quality improvement. The Agency is seeking comment on whether the final rule should modify some of the requirements or permit payment of some or all of the payment depending on the severity of noncompliance and other factors.

As previously stated, CMS is proposing that Technical participants will not qualify for Track One status but rather be deemed Track Two. While this prevents them from being considered Advanced APMs or MIPS APMs, they can still attest to their participation in an APM for the purposes of MIPS and may receive an Improvement Activity credit. If a Technical participant at a freestanding center begins providing PC services at any point during the model performance period, they must notify CMS within 30 days. CMS is proposing that they would be required to report quality measures by the next reporting period, which would be March of a PY for Quality Measures and January and July of a PY for CDEs. Furthermore, if they meet the requirements to be a Track One RO Model participant at one of the QP determination dates (March 31, June 30, or August 31), they would be considered participating in an Advanced APM and a MIPS APM. CMS invites stakeholder input on this proposal.

Individual Practitioner List

At the start of each PY, CMS creates and provides to each RO participant that is a PGP or a freestanding radiation therapy center an individual practitioner list identifying by NPI each individual practitioner associated with the RO participant. In the 2020 Specialty Care Models final rule, CMS established a requirement that RO Participants must review and certify individual practitioner lists within 30 days of receipt of the list. The Agency also requires participants to notify CMS within 30 days if there are any additions or removals of eligible clinicians to the individual practitioner list.

In the 2022 HOPPS proposed rule, CMS is proposing to modify these requirements so that RO participants have the ability to review their individual practitioner list and add or drop the necessary NPIs from the list up until the last QP determination snapshot date (August 31). This will allow more time for RO participants to review and certify their individual practitioner lists. CMS seeks comment on this proposal.

CMS is also proposing to provide Technical participants with an individual practitioner list. If individual practitioners who participate in the RO Model with Technical participants that are freestanding radiation therapy centers are not included on a verified list, they will not be eligible to receive Improvement Activity credit under MIPS as previously described. Additionally, in the case of a Dual, Professional, or Technical participant that is a freestanding radiation therapy center, which begins participation in the RO Model after the start of a given PY, but at least 30 days prior to the last QP determination snapshot date of that PY (August 31), CMS proposes to create and provide the new participant with an individual practitioner list that they must certify by the last QP determination snapshot date. CMS believes this proposal will give all RO participants, including those that begin participation in the RO Model after the start of the PY, more time to review and certify their individual practitioner lists.

Model Overlap

According to CMS, there is the 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. The Agency proposes to continue reviewing potential overlap in these situations and pursue any future changes through ACO initiative procedures.

Extreme and Uncontrollable Circumstances

In the 2022 HOPPS Proposed Rule, CMS is proposing to adopt an Extreme and Uncontrollable Circumstances (EUC) policy for the RO Model, which would allow the Agency to revise the model performance period; grant certain exceptions to RO Model requirements to ensure delivery of safe and efficient health care; and revise the RO Model's payment methodology.

The Agency is proposing to define an EUC as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to delivery care in accordance with the RO Model's requirements and affects the entire region or locale. CMS proposes that if it declares an EUC for a geographic region, then it may 1) amend the model performance period; 2) eliminate or delay certain reporting requirements for RO participants; and 3) amend the RO Model's pricing methodology.

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

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

In the event that one or more of these conditions are present, CMS would announce that an EUC policy applies to one or more RO participants within an affected geographic area. The Agency seeks public comment on this proposal.

In instances where an EUC is nation-wide and impacts RO participants' ability to implement the requirements of the RO Model at the start of the model performance period, CMS proposes to delay the start date of the model performance period by up to one calendar year. RO Participants would be notified of any changes to the model performance period on the RO Model website no later than 30 days prior to the original start date. In the case where a delay to the RO Model performance period is required due to an EUC, other aspects of the RO Model may be impacted, including status as an Advanced APM and the years that would be included in the baseline period. In the case of a regional EUC, CMS is proposing not to change the model performance period, but instead only to delay or exempt requirements for RO participants in the impacted region.

If an EUC impacts a RO participants' ability to comply with the RO Model's quality measure or clinical data elements reporting requirements, CMS is proposing that it may delay or exempt the affected RO participants from reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS, as applicable.

If CMS decides to remove quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, CMS proposes that it may choose to repay the quality withhold during the next reconciliation period and award all possible points in the subsequent AQS calculation for affected RO participants.

In situations in which RO participants nation-wide experience significant, aggregate-level disruptions to their service utilization, in that the trend factor (specific to a cancer type and component) for the upcoming PY has increased or decreased by more than 10 percent compared to the corresponding trend factor of the previous CY when FFS payments are held constant with the previous CY, CMS is proposing that it may modify the trend factor calculation for the PC and/or TC of an included cancer type. If CMS were to implement this modification, it would ensure that the trend factor calculation is most consistent with the average utilization from the previous CY.

Because RO participants must focus on direct care, CMS is proposing that it may waive compliance with or adjust the requirement that RO participants actively engage with AHRQ-listed patient safety organization (PSO) and provide Peer Review on treatment plans.

COVID-19

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

Additional Resources

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

Final rule language: https://public-inspection.federalregister.gov/2021-15496.pdf

CMS Fact Sheet: https://www.cms.gov/newsroom/fact-sheets/cy-2022-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

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