2022 Radiation Oncology Model
Final Rule

The Radiation Oncology Alternative Payment Model (RO Model) final rule was issued on November 2, 2021 in conjunction with the 2022 Hospital Outpatient Prospective Payment System (HOPPS) and Ambulatory Surgical Center (ASC) Payment System final rule. The final rule will be published in the November 16th *Federal Register*. All payments and policies are effective on January 1, 2022.

The Centers for Medicare and Medicaid Services (CMS) notes that they are **finalizing the majority of the proposals without modification, and there are two proposals that they finalizing with modification. These include the definitions for RO Track One and RO Track Two, as well as the extreme and uncontrollable circumstances (EUC) policy.**

CMS included in the model an extreme and uncontrollable circumstances policy, associated with the COVID-19 Public Health Emergency (PHE), that will grant RO Model participants some flexibility on quality reporting and monitoring requirements in the first performance year (PY1).

According to the final rule, the EUC policy will provide RO Model participants with the option to collect and submit quality measures and clinical data elements (CDEs) in PY1. As a result, the 2% quality withhold will be removed from the payment methodology. Additionally, the Agency is making the requirements associated with participating in an AHRQ-listed Patient Safety Organization (PSO) and conducting peer review optional in PY 1. Should the Secretary of Health and Human Services (HHS) terminate the renewal of the PHE prior to January 1, 2022, then the EUC policy will also be terminated, and quality measure and CDE reporting will be mandatory.

As a result of the flexibility granted through the EUC, RO Model participants will not have to comply with these reporting requirements in order to be deemed eligible for Advanced APM status and to receive the 5% bonus associated with Advanced APM participation.

Impact of RO Model

The RO Model remains a mandatory model encompassing 30 percent of all eligible radiotherapy (RT) episodes (these occur in 204 eligible Core-Based Statistical Areas (CBSAs) in 48 states and the District of Columbia). Revising the model performance period to begin January 1, 2022 would not affect the estimated 500 Physician Group Practices (of which 275 are freestanding radiation therapy centers) or 450 Hospital Outpatient Departments that CMS expects to furnish RT services in the selected CBSAs.

CMS expects the model performance period that begins January 1, 2022, and ends December 31, 2026, will include approximately 282,000 episodes, 250,000 beneficiaries, and $4.6 billion in total episode spending of allowed charges over the Model performance period.

CMS estimates that on net the Medicare program would save $150 million over the 5-year model performance period, which is a modest decrease from the anticipated $160 million in savings anticipated in the 2022 proposed rule.

CMS estimates that on average, Medicare fee-for-service (FFS) payments to Physician Group Practices (PGPs) will increase by 6.3% and Medicare FFS payments to Hospital Outpatient Departments (HOPDs) will decrease by 9.9% over the duration of the model demonstration period. The shifts in payment are due to the site neutral payment methodology that the RO Model seeks to test, which increases PGP Medicare FFS payments and decreases HOPD Medicare FFS payments. These estimates do not include changes to the Clinical Labor Price inputs that

were included in the 2022 Medicare Physician Fee Schedule (MPFS) final rule. According to the final rule, the Clinical Labor Price input updates would result in an increase of 10.2% for PGPs and a decrease of 11.3% for HOPDs over the lifetime of the RO Model. The table below demonstrates estimated impact by year based on data that does not include the Clinical Labor Price input update.

Radiation Oncology Model PGP vs. HOPD Allowed Charges Impacts 2022-2026

% Impact	2022	2023	2024	2025	2026	2022-2026
PGP	3.1%	4.5%	6.0%	7.4%	8.9%	6.3%
HOPD	-7.8%	-8.8%	-9.6%	-10.6%	-11.6%	-9.9%

Background

On September 29, 2020, CMS published the final rule entitled “Specialty Care Models to Improve Quality of Care and Reduce Expenditures” and codified policies at 42 CFR part 512. The RO Model is designed to test whether prospective episode-based payments for radiotherapy (RT) services (also referred to as radiation therapy services) will reduce Medicare program expenditures and preserve or enhance quality of care for beneficiaries. As radiation oncology is highly technical and furnished in well-defined episodes, and because patient comorbidities generally do not influence treatment delivery decisions, CMS believes that radiation oncology is well-suited for testing a prospective episode payment model. Under the RO Model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. The RO Model will include 30 percent of all eligible RT episodes. CMS finalized that the base payment amounts for RT services included in the RO Model would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. CMS finalized that the model performance period would be five performance years (PYs), beginning January 1, 2021, and ending December 31, 2025, with final data submission of clinical data elements and quality measures in 2026 to account for episodes ending in 2025.

To ensure that participation in the RO Model during the public health emergency (PHE) for the COVID-19 pandemic did not further strain RO participants' capacity, CMS revised the RO Model's model performance period to begin on July 1, 2021, and end December 31, 2025, in the 2021 HOPPS and ASC Payment Systems final rule. In the 2021 HOPPS/ASC final rule, CMS changed the duration of the model performance period from 5 years to 4.5 years, changed the timelines for the submission of clinical data elements (CDEs), quality measures and Certified Electronic Health Record Technology (CEHRT) requirements, and modified the eligibility dates of the RO Model as an Advanced Alternative Payment Model (APM) and Merit-based Incentive Payment System (MIPS) APM.

Section 133 of the Consolidated Appropriations Act (CAA), 2021, enacted on December 27, 2020, included a provision that prohibited implementation of the RO Model before January 1, 2022. This Congressional action supersedes the RO Model delayed start date established in the 2021 HOPPS/ASC final rule.

Model Performance Year

CMS modified the model performance period to begin on January 1, 2022, and end December 31, 2026. No new RT episodes may begin after October 3, 2026, in order for all RT episodes to end by December 31, 2026. **CMS also finalized the proposal that 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, unless the initial model performance period starts mid-year, in which case PY1 will begin on that date and end on December 31 of that year.

Definitions

CMS finalized the proposal to add a definition for "baseline period", specifying which episodes (dependent on the model performance period) are used in the pricing methodology. **CMS defines "baseline period"** to mean the three calendar year (CY) period that begins on January 1 no fewer than five years but no more than six 6 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 would be January 1, 2017 through December 31, 2019,** unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period would be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

CMS modifies the definition of the "model performance period" to mean the five PYs during which RT episodes must initiate and terminate. The model performance period would begin on January 1, 2022 and end on December 31, 2026, unless the RO Model is prohibited by law from starting on January 1, 2022, in which case the model performance period would begin on the earliest date permitted by law that is January 1, April 1, or July 1.

CMS modifies the definition of "PY" (performance year) to mean each 12-month period beginning on January 1 and ending on December 31 during the model performance period, unless the model performance period begins on a date other than January 1, in which case, the first performance year (PY1) would begin on that date and end on December 31 of the same year.

CMS modifies the definition of "stop-loss reconciliation amount" to mean the amount owed by CMS for the loss incurred 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.

Participant Exclusions

Pennsylvania Rural Health Model:

CMS finalized the proposal that HOPDs that are identified as eligible to participate in the Pennsylvania Rural Health Model (PARHM), but that are not current PARHM participants, should be included in the RO Model if they are located in a CBSA selected for participation in the RO Model and that this exclusion of HOPDs associated with hospitals that participate in PARHM from the RO Model would apply only during the period of such participation.

Community Health Access and Rural Transformation Model:

CMS finalized the proposal to modify the exclusions from the RO Model so that the HOPD of any participating hospital in the Community Transformation Track of the Community Health Access and Rural Transformation (CHART) Model is excluded from the RO Model.

Low Volume Opt-Out:

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 final rule that episodes furnished prior to the start of the model performance period in CBSAs selected for participation will be used to determine eligibility of the low volume opt-out for PY1 and PY2. If PY1 begins on January 1, RT episodes will be used to determine the eligibility of the low volume opt-out for PY3. If PY1 begins on any date other than January 1, both RT episodes of PY1 and episodes occurring in the CY of PY1 (but occurring prior to the start of PY1 in that year) in CBSAs selected for participation will be used to determine the eligibility of the low volume opt-out for PY3. RT episodes of PY2 and PY3 will be used to determine the eligibility of the low volume opt-out for PY4 through PY5, respectively.

CMS states that an entity would not be eligible for the low volume opt-out if its legacy TIN or legacy 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.

A legacy CCN means a CCN that an 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 an 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 included RT services.

By finalizing these proposals, CMS is removing any incentive for RO participants to change their TIN or CCN in an effort to become eligible for the low volume opt-out.

Changes to RO Model Episodes

Criteria for Determining Included Cancer Types:

CMS proposed to amend regulatory text 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; and the Secretary must not have determined that the cancer type is not suitable for inclusion in the RO Model. **CMS finalized the proposal that they will remove from the RO Model a cancer type that does not meet all three of these criteria or for which CMS discovers a > 10 percent error in established national base rates.**

Removal of Liver Cancer from Included Cancer Types:

After conversations with radiation oncologists consulting on the RO Model and additional reviews of the latest literature, CMS believes that the inclusion of liver cancer does not meet the inclusion criteria because liver cancer is not commonly treated with radiation per nationally recognized, evidence-based clinical treatment guidelines. **CMS finalized the proposal to remove liver cancer from the RO Model as an included cancer type**.

Below is the updated list of cancer types and included ICD-10 codes:

Cancer Type	**ICD-10 Codes**
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.51
Brain Metastases	C79.3x
Breast Cancer	C50.xx, D05.xx
Cervical Cancer	C53.xx
CNS Tumors	C70.xx, C71.xx, C72.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.xx, 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, C91.4x
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

Removal of Brachytherapy from Included RT Services:

In response to the publication of proposed and final rules, CMS received stakeholder feedback encouraging the Agency to reconsider how multimodality episodes-- which are episodes involving two or more types of RT treatment--are handled in the RO Model, especially in the cases of cervical cancer and prostate cancer, where standard clinical practice is concordant treatment with external beam radiation therapy (EBRT) and brachytherapy. Stakeholders expressed concern that the RO episode-based payment does not account for multimodality care. Stakeholders were particularly concerned about cases where the RO participant furnishing the external beam radiation therapy is different from the RO participant providing brachytherapy. Stakeholders suggested creating a separate bundled payment for brachytherapy or removing it from the RO Model. CMS also heard continued concern from some stakeholders about the inclusion of the brachytherapy sources, particularly fast-acting radioisotopes, in the bundled payments, because they are more like medical devices used in conjunction with medical procedures than other modalities. Brachytherapy sources are also typically paid for separately.

Some stakeholders suggested that inclusion of brachytherapy in the bundled payments could lead to reduced utilization of brachytherapy in situations where a combination of brachytherapy and EBRT is clinically indicated (particularly for cervical and prostate cancers). Stakeholders expressed concern that in the case of multimodality treatment including brachytherapy, there may be a disincentive to refer patients to other radiation oncologists for treatment when the RO participant cannot deliver brachytherapy services themselves.

According to the final rule, CMS does not seek to either incentivize nor discourage the use of one modality over another, but rather to encourage providers to choose RT services that are the most clinically appropriate for beneficiaries under their care. The exclusion of a modality from the RO Model is not meant to imply anything about the value of such modality. Published clinical evidence suggests brachytherapy is a high-value RT service, which could warrant its inclusion in the RO Model. However, CMS acknowledges the concerns stakeholders have about possible unintended consequences for beneficiaries' access to care.

CMS finalized the proposal to amend regulatory text to remove brachytherapy as an included modality in the RO Model.

CMS' removal of brachytherapy from the RO Model would render the waiver of section 1833(t)(2)(H) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) moot, and therefore CMS is withdrawing this waiver. The MMA legislation mandates separate payment for brachytherapy sources in the hospital outpatient setting.

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

77014	CT guidance placement radiation fields	77412	Radiation treatment delivery
77021	MRI guidance needle placement	77417	Radiology port images
77261	Treatment planning, simple	77427	Radiation treatment management, weekly
77262	Treatment planning, intermediate	77431	Radiation therapy management
77263	Treatment planning, complex	77432	SRS management
77280	Simulation, simple	77435	SBRT management
77285	Simulation, intermediate	77470	Special treatment procedure
77290	Simulation, complex	77499	Treatment management unlisted
77293	Respiratory motion management simulation	77520	Proton treatment delivery, simple without compensation
77295	3D simulation	77522	Proton treatment delivery, simple with compensation
77299	Treatment planning unlisted	77523	Proton treatment delivery, intermediate
77300	Basic radiation dosimetry calculation	77525	Proton treatment delivery, complex
77301	IMRT planning	G0339	Robotic linear accelerator SRS, first session
77306	Teletherapy isodose plan, simple	G0340	Robotic linear accelerator SRS, fractions 2-5
77307	Teletherapy isodose plan, complex	G6001	U/S guidance radiotherapy
77321	Special teletherapy port plan	G6002	Stereoscopic x-ray guidance
77331	Special dosimetry	G6003	Radiation treatment delivery
77332	Treatment devices, simple	G6004	Radiation treatment delivery
77333	Treatment devices, intermediate	G6005	Radiation treatment delivery
77334	Treatment devices, complex	G6006	Radiation treatment delivery
77336	Medical physics consult	G6007	Radiation treatment delivery
77338	Treatment device, MLC IMRT	G6008	Radiation treatment delivery
77370	Special medical physics consult	G6009	Radiation treatment delivery
77371	SRS treatment delivery, multisource	G6010	Radiation treatment delivery
77372	SRS treatment delivery, linear based	G6011	Radiation treatment delivery
77373	SBRT treatment delivery	G6012	Radiation treatment delivery
77385	IMRT delivery, simple	G6013	Radiation treatment delivery
77386	IMRT delivery, complex	G6014	Radiation treatment delivery
77399	Physics, dosimetry, treatment devices unlisted	G6015	IMRT treatment delivery
77402	Radiation treatment delivery	G6016	MLC-based IMRT treatment delivery
77407	Radiation treatment delivery	G6017	Intrafraction track motion

Exclusion of Intraoperative Radiotherapy (IORT):

CMS finalized that Intraoperative Radiotherapy (IORT)—a technique that involves precise delivery of a large dose of ionizing radiation to the tumor or tumor bed during surgery—would not be included in the RO Model. CMS received comments from stakeholders requesting that they re-evaluate this decision and include IORT in the RO Model and will consider these comments in future rulemaking.

Pricing Methodology

Secondary Diagnoses & Assignment of Cancer Types to an Episode:

In the 2020 Specialty Care Models final rule, CMS reiterated 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 the final 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.

Constructing Episodes Using Medicare FFS Claims and Calculation of Episode Payment:

Although CMS is removing references to specific CYs from the definition of baseline period, CMS still constructs 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. Furthermore, although CMS is removing references to specific CYs, CMS will continue to weigh the most recent observations more heavily than those that occurred in earlier years, as previously finalized. **In the 2022 final rule, CMS weighted 2017 data at 20%, 2018 data at 30%, and 2019 data at 50%.**

CMS codified that for sequestration, they deduct 2% from each episode payment after applying the trend factor, geographic adjustment, case mix and historical experience adjustments, discount, withholds, and coinsurance to the national base rate. At times, the requirements for sequestrations are modified by legislation or regulation. Therefore, CMS is amending regulatory text by removing the percentage amount and indicating that sequestration will be applied in accordance with applicable law.

Baseline Period:

As noted above, CMS finalized its proposal to define a “baseline period.” The table below summarizes the data sources and time periods used to determine the values of key pricing components for a baseline period of 2017 through 2019 as a result of the modified pricing methodology.

Key Components	Data Source	PY 1 (2022)	PY 2 (2023)	PY 3 (2024)	PY 4 (2025)	PY 5 (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)	(2013 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-specific	2017-2019	2018-2020	2019-2021	2020-2022	2021-2023
Historical Experience Adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant-specific	2017-2019	2017-2019	2017-2019	2017-2019	2017-2019
Blend for RO Participant with historical experience adjustment greater than 0.0	N/A	0.90	0.85	0.80	0.75	0.70
Blend for RO Participant with historical experience adjustment equal to or less than 0.0	N/A	0.90	0.90	0.90	0.90	0.90
RVU shares used in the MPFS 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) 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	Work/PE/MP Shares PC (66/30/4) TC (0/99/1) 2019
Low Volume Opt-Out eligibility (<20 episodes)	Participant-specific	2020	2021	2022	2023	2024

National Base Rates:

In the 2022 final rule, CMS excludes all Maryland, Vermont, and U.S. Territory claims and all CAH, inpatient, ASC, and PPS-exempt claims from episode construction, attribution and pricing. CMS is also finalizing the proposal to exclude all claims of an HOPD participating in PARHM, as well as episodes that are attributed to an RT provider or RT suppliers that is located in a zip code not assigned to a CBSA for model participation.

The baseline period is January 1, 2017 through December 31, 2019, unless the RO Model is prohibited by law from starting in CY 2022, in which case the baseline period will be adjusted according to the new model performance period (that is, if the model performance period starts any time in CY 2023, then the baseline period would be CY 2018 through CY 2020).

Further, CMS is clarifying that Part B expenditures during the baseline period would be used to establish separate PC and TC national base rates for each of the included cancer types, the participant-specific historical experience adjustments for the model performance period, and the participant-specific case mix adjustments for PY1. The case mix adjustments for subsequent PYs (PY2 to PY5) would be calculated using the case mix model from the baseline period with the inputs coming from the beneficiary characteristics in episodes attributed to the participant in the most recent 3-year period that ends 3 years prior to the start of the CY to which the participant-specific case mix adjustment would apply.

CMS modified the National Base Rates based on the updated baseline period, as well as the decision to remove brachytherapy from the list of included modalities and liver cancer from the list of cancer types included in the RO Model. The National Base Rates set for 2022 did not change from the proposed rates. The finalized national base rates for the model performance period are summarized below.

RO Model-Specific Codes	Professional or Technical	Cancer Type	Base Rate
M1072	Professional	Anal Cancer	$3,104.11
M1073	Technical	Anal Cancer	$16,800.83
M1074	Professional	Bladder Cancer	$2,787.24
M1075	Technical	Bladder Cancer	$13,556.06
M1076	Professional	Bone Metastases	$1,446.41
M1077	Technical	Bone Metastases	$6,194.22
M1078	Professional	Brain Metastases	$1,651.56
M1079	Technical	Brain Metastases	$9,879.40
M1080	Professional	Breast Cancer	$2,059.59
M1081	Technical	Breast Cancer	$10,001.84
M1082	Professional	CNS Tumor	$2,558.46
M1083	Technical	CNS Tumor	$14,762.37
M1084	Professional	Cervical Cancer	$3,037.12
M1085	Technical	Cervical Cancer	$13,560.15
M1086	Professional	Colorectal Cancer	$2,508.30
M1087	Technical	Colorectal Cancer	$12,200.62
M1088	Professional	Head & Neck Cancer	$3,107.95
M1089	Technical	Head & Neck Cancer	$17,497.16
M1094	Professional	Lung Cancer	$2,231.40
M1095	Technical	Lung Cancer	$12,142.39
M1096	Professional	Lymphoma	$1,724.07
M1097	Technical	Lymphoma	$7,951.09
M1098	Professional	Pancreatic Cancer	$2,480.83
M1099	Technical	Pancreatic Cancer	$13,636.95
M1100	Professional	Prostate Cancer	$3,378.09
M1101	Technical	Prostate Cancer	$20,415.97
M1102	Professional	Upper GI Cancer	$2,666.79
M1103	Technical	Upper GI Cancer	$14,622.66
M1104	Professional	Uterine Cancer	$2,737.11
M1105	Technical	Uterine Cancer	$14,156.20

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 final rule, CMS is modifying 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 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 trend factor calculation for PY 1 (2022) follows:

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

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 issuance of the annual HOPPS and MPFS final rules. This means practices have less than two months to understand their payment rates for the coming PY, which may be inadequate for practices to understand the model's impact.

Applying the Adjustments:

CMS clarified that the total number of RO participant-specific episode payments for Dual participants and the total number of RO participant-specific episode payments for Professional participants and Technical participants will vary depending on the number of included cancer types. For example, 15 included cancer types would yield a total of 30 RO participant-specific episode payment amounts for Dual participants and a total of 15 RO participant-specific episode payment amounts for Professional participants and Technical participants.

HOPD or Freestanding Radiation Therapy Center With Fewer Than Sixty Episodes During the Baseline Period:

CMS modified the stop-loss limit policy such that it applies to RO participants that have fewer than 60 episodes during the baseline period and that were furnishing included RT services any time before the start of the model performance period in the CBSAs selected for participation.

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

To address related payment adjustments, CMS calculates the RO participant's case mix adjustments based on all episodes and RT episodes, as applicable, attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the 3-year period that determines the case

mix adjustment for each PY and all episodes and RT episodes, as applicable, attributed to the RO participant's current TIN or CCN during the 3-year period that determines the case mix adjustment for each PY.

Similarly, CMS calculates the RO participant's historical experience adjustments based on all episodes attributed to the RO participant's legacy TIN(s) or legacy CCN(s) during the baseline period and all episodes attributed to the RO participant's current TIN or CCN during the baseline period.

In the 2022 final rule, CMS eliminates 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. CMS requires an RO participant furnish to CMS written notice of a change in TIN or CCN in a form and manner specified by CMS at least 90 days before the effective date of any change in TIN or CCN that is used to bill Medicare.

CMS continues to believe that some new or altered clinical or business relationships may still pose risks of gaming in the RO Model, regardless of whether a change in control results. However, they believe that requiring RO participants to report changes to TINs or CCNs will capture the types of changes that pose these risks. This would also avoid any ambiguity as to what types of changes RO participants would need to report.

Discount Factor:

CMS finalized the proposal to lower the discount factor for the PC to 3.5%t and the discount factor for the TC to 4.5%. CMS states that they have made every effort to be responsive to stakeholder requests to lower the discount factor. CMS states that they cannot further reduce the discounts beyond 3.5% and 4.5% for the PC and TC, respectively, without changing other aspects of the Model, such as increasing the size of the Model.

Withholds:

CMS finalized the proposal that RO participants submit quality measure data starting in PY1 (when the model performance period begins), and that beginning in PY1, a 2% quality withhold for the PC would be applied to the applicable trended national base rates after the case mix and historical experience adjustments.

Due to the continued PHE, CMS is applying the previously mentioned EUC policy that will waive the 2% withhold for PY1 for all participants. Should the Secretary of HHS terminate the renewal of the COVID-19 PHE prior to January 1, 2022, then the 2% withhold would be applied in PY1.

Adjustment for Geography:

CMS modifies this provision to align with the model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. For the baseline period of 2017-2019, 2019 would be used to calculate the implied RVU shares.

Examples of Participant-Specific Professional Episode Payment and Participant-Specific Technical Episode Payment for an Episode Involving Lung Cancer in PY1:

CMS noted in the proposed rule that they are currently analyzing whether the COVID-19 pandemic resulted in a decrease in Medicare FFS claims submissions for RT services during 2020 relative to historical levels. For this reason, **under the extreme and uncontrollable policy, pending 12-months of claims run-out for RT services furnished in 2020, CMS will consider the removal of 2020 data from the calculation of any applicable baseline period or trend factor.** CMS is not considering the exclusion of 2020 from the case mix adjustment at this time,

because the case mix episodes are weighted equally (unlike the baseline period, where more recent episodes are given more weight than earlier episodes), and the case mix adjustment does not rely on the volume of RT services furnished.

Quality--Form, Manner and Timing for Quality Reporting

CMS finalized the proposal that Professional participants and Dual participants submit quality measure data starting in PY1 during the model performance period.

For PY1, 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. Professional participants and Dual participants would be required to submit data on a fourth measure, Treatment Summary Communication—Radiation Oncology, as a pay-for-reporting measure. All quality measure data is reported using the RO Model secure data portal in the manner consistent with that submission portal and the measure specification.

Data submitted by Professional participants and Dual participants for the Treatment Summary Communication—Radiation Oncology measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure, for PY3.

CMS finalized the proposal that they may update the specifications for the Treatment Summary Communication – Radiation Oncology measure, should new specifications from the measure's steward meet the RO Model's needs. Any non-substantive updates to the specifications for this measure would be communicated in a form and manner specified by CMS. Any substantive changes to measure specifications would be addressed through notice and comment rulemaking.

Given the change in model performance period due to the delay under CAA 2021, **CMS finalized the proposal that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy as soon as there are completed RT episodes, no earlier than the fourth month of the model performance period.**

CMS finalized under the RO Model's clinical data collection policy that Professional participants and Dual participants submit CDE data starting in PY1 of the model performance period.

The RO Model as an Advanced Alternative Payment Model (Advanced APM) and a Merit-Based Incentive Payment System APM (MIPS APM)

Despite the delay required by the CAA 2021, CMS expects the RO Model to meet the criteria to be an Advanced APM and a MIPS APM beginning January 1, 2022 (PY1). Final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at https://qpp.cms.gov/. CMS anticipates that the RO Model will meet the Advanced APM criteria in PY1 and all subsequent PYs.

The criterion to be an Advanced APM include:

1. Certified electronic health record technology (CEHRT) use
2. Payment based on quality measures
3. Financial risk

In the 2022 final 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.

CMS modified the Track One and Track Two proposal, as established in the proposed rule, by splitting the Track One component into two tracks, establishing Tracks One, Two and Three in the final rule.

Track One will be for RO participants who comply with all RO requirements, including CEHRT. Track One RO Participants will be considered either Advanced APMs and MIPS APMs.

Track Two will be for those RO participants who comply with all RO Model requirements except for CEHRT, therefore making these participants MIPS APMs.

Track Three will be for all other RO participants who will not be considered either an Advanced APM or MIPS APM.

CMS states that by establishing the new Track Two category, those RO participants who do not certify their use of CEHRT can be eligible for MIPS APM reporting and scoring pathways. The Agency believes this lessens the burden of the CEHRT requirement.

Technical Participants and the Quality Payment Program:

Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component (TC) are not required to report quality measures under the RO Model and will not be participating in (final rule modified) Track One or Track Two of the RO Model, and therefore Technical participants would not be participants in Advanced APMs or MIPS APMs under the RO Model. However, Technical participants can attest to their participation in an APM for purposes of MIPS, and may be eligible to receive Improvement Activity credit.

CMS finalized the proposal that if Technical participants that are freestanding radiation therapy centers (as identified by a TIN) begin providing the PC at any point during the model performance period, then they must notify CMS within 30 days, in a form and manner specified by CMS. CMS notes that they would also be required under the RO Model 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 the clinical data elements. If they meet the requirements to be a Track One RO Model participant at one of the QP determination dates specified, they would be considered to be participating in an Advanced APM and a MIPS APM. Once a Technical participant that is a freestanding radiation therapy center begins providing the professional component, the freestanding radiation therapy center becomes a Dual participant. CMS will monitor these RO participants for compliance with the requirement to report quality measures if they begin providing the professional component.

RO Model Requirements:

CMS codified that RO participants must use CEHRT, that the RO participant must annually certify its use of CEHRT during the model performance period, and that the RO participant will be required to certify its use of CEHRT within 30 days of the start of each PY.

CMS finalized the proposal that the CEHRT requirement would begin in PY1 of the model performance period and that RO participants must certify their use of CEHRT at the start of PY1 and each subsequent PY.

Reconciliation Process

Initial Reconciliation:

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. Given the change in model performance period due to the delay under CAA 2021, **CMS expects to conduct the initial reconciliation each August for the preceding PY.** For example, for PY1, CMS would conduct the initial reconciliation as early as August of PY2.

CMS finalized the proposal that beginning in PY1, a 2% quality withhold for the PC will be applied to the applicable trended national base rates after the case mix and historical experience adjustments. CMS is finalizing as proposed that the application of a quality withhold will begin in PY1.

In the CY 2021 HOPPS/ASC final rule, CMS amended that the quality reconciliation payment amount would not be applicable for PY1, because there would not be a quality withhold in PY1. Given the change in model performance period due to the delay under CAA 2021, and that the application of a quality withhold would begin in PY1, CMS is amending regulatory text such that the quality reconciliation payment amount will apply to all PYs.

True-Up Reconciliation:

The true-up reconciliation is the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial reconciliation and after a 12-month claims run-out for all RT episodes initiated in the applicable PY. Given the change in model performance period due to the delay under the CAA 2021, **CMS expects to conduct the true-up reconciliation as early as August of the CY following an initial reconciliation for a PY.** For example, for PY1, CMS would conduct the true-up reconciliation as early as August of PY3.

Reconciliation Amount Calculation:

CMS modified this policy such that for all incomplete episodes, including when the RO beneficiary ceases to have traditional FFS Medicare before all included RT services in the RO episode have been furnished, CMS would 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 data for incomplete episodes, including incomplete episodes where an RO beneficiary ceases to have traditional FFS Medicare before the end of an episode, CMS determined that the data did not support paying RO participants only the first installment of an episode for this type of incomplete episode. Upon further review of this data and stakeholder comments on this policy, **CMS amends this policy that these services will be paid FFS instead of under the RO Model.**

In light of the proposal to modify payment for incomplete episodes, CMS is proposing conforming changes regarding beneficiary coinsurance for incomplete episodes. Specifically, **CMS modifies regulatory text to specify that the coinsurance for all incomplete episodes is 20 percent of the FFS amount applicable to the RT services that were furnished.**

CMS modifies the definition for "stop-loss reconciliation amount" to mean the amount owed to RO participants that have fewer than 60 episodes during the baseline period (2017-2019) and were furnishing included RT services before the start of the model performance period in the CBSAs selected for participation for the loss incurred under the RO Model.

Potential Overlap with Other CMS Programs and Models

CMS continues to see no need to adjust the prospective episode payments made under the RO Model to reflect payments made under the Shared Savings Program or under any other models tested under section 1115A of the Act at this time. CMS codified their overlap policy.

Extreme and Uncontrollable Circumstances Policy

The U.S. is currently responding to an outbreak of respiratory disease caused by a novel coronavirus, referred to as "COVID-19", which has created serious public health threats that have greatly impacted the U.S. health care system, presenting significant challenges for stakeholders across the health care delivery system and supply chain. Other extraordinary events that have a disruptive impact may also occur in the future. These events may include other public health emergencies, large-scale natural disasters (such as, but not limited to, hurricanes, tornadoes, and wildfires), or other types of disasters. Such events may strain health care resources, and CMS understands that RT providers and RT suppliers may have limited capacity to continue normal operations and fulfill RO Model participation requirements under such circumstances. Therefore, **CMS finalized the proposal to adopt an extreme and uncontrollable circumstance policy for the RO Model which would allow CMS to revise the model performance period; grant certain exceptions to RO Model requirements to ensure the delivery of safe and efficient health care; and revise the RO Model's payment methodology.**

Extreme and Uncontrollable Circumstance Affects the Nation, Region, or a Locale:

CMS defines an extreme and uncontrollable circumstance (EUC) as a circumstance that is beyond the control of one or more RO participants, adversely impacts such RO participants' ability to deliver care in accordance with the RO Model's requirements, and affects an entire region or locale.

If CMS declares an EUC for a geographic region, **CMS 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.** Application of the modifications would be based on the severity and types of challenges that the circumstance imposes on RO participants. In every circumstance, CMS would seek to minimize impact on the RO participants not affected by the EUC, while supporting those that are affected.

Model Performance Period:

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 may 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.

Reporting Requirements:

Quality Measures and Clinical Data Elements: If an EUC impacts RO participants' ability to comply with the RO Model's quality measure or clinical data element reporting requirements, **CMS finalized the proposal to delay or exempt the affected RO participants from the reporting requirements, make the requirements optional, and/or extend the time for RO participants to report data to CMS, as applicable, or both.**

Other Participation Requirements: Because RO participants must focus on direct care, **CMS finalized the proposal that CMS may waive compliance with or adjust the requirement that RO participants actively engage with an AHRQ-listed patient safety organization (PSO) and provide Peer Review (audit and feedback) on treatment plans.**

Pricing Methodology:

Adjusting the Quality Withhold: **CMS is finalizing with modification that if CMS were to remove (not merely extend the submission window) quality and clinical data submission requirements for affected RO participants due to a national, regional, or local event, CMS could choose to repay the quality withhold during the next reconciliation, and award all possible points in the subsequent AQS calculation for affected RO participants, which would potentially increase episode payments during this time.**

Trend Factor Adjustments: In situations where 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 payment rates are held constant with the previous CY, **CMS may modify the trend factor calculation for the PC and/or TC of an included cancer type.**