

ISSUES | Radiation Oncology Model

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Addendum: On December 10, 2021, President Biden signed into law the Protecting Medicare and American Farmers from Sequester Cuts Act. The new law delays implementation of the Radiation Oncology Alternative Payment Model (RO Model) until January 1, 2023. The model was originally scheduled to begin January 1, 2022, per legislation at the end of December 2020.

The following summary outlines the highlights and/or changes the Centers for Medicare & Medicaid Services (CMS) made related to the Radiation Oncology (RO) Model. This information includes some graphics from the proposed rule, as they were not included in the final rule. This is not a comprehensive summary and readers are encouraged to access additional resources and information on the RO Model website: innovation.cms.gov/innovation-models/radiation-oncology-model.

Due to the episodic nature of radiation oncology's courses of treatment, CMS continues to believe that radiation oncology is better suited for a payment model. The premise of the RO Model is to collect data over a set period of time to better analyze the practice patterns of a randomized demographic of radiation oncology providers and physicians as well as physician group practices, hospitals, and freestanding centers. The results will allow for the promotion of quality and financial accountability for episodes of care for radiation oncology services and ultimately reduce spending for Medicare beneficiaries treated with radiation.

Payments will be site-neutral, meaning the same amount is paid when services are performed in a hospital outpatient department, physician practice, or freestanding center. This site neutrality will provide greater predictability of payments and manage episodes clinically rather than driven by fee-for-service payments and incentives. In other words, the differences that currently exist in the Hospital Outpatient Prospective Payment System (HOPPS) and Medicare Physician Fee Schedule (MPFS) payment systems do not exist in the RO Model.

Timeline of the RO Model

Since the initial final rule detailing the timeline for the RO Model, there have been several changes to the start date. Originally scheduled to start January 1, 2021, the RO Model was delayed as part of the CY 2021 HOPPS final rule, with a start date of July 1, 2021. After Congressional action and as part of the Consolidated Appropriations Act of 2021, the RO Model legally could not start prior to January 1, 2022. Per the HOPPS CY 2022 final rule, the RO Model begins on January 1, 2022, and runs through December 31, 2026. As CMS indicated, this timeline is pending no legal or additional Congressional intervention. The agency also indicated no episodes of care could begin after October 3, 2026, to allow for treatment completion prior to the scheduled end date on December 31, 2026.

New Definitions

CMS added and updated a few definitions to the RO Model:

- **EUC (extreme and uncontrollable circumstances):** A circumstance that is beyond the control of one or more RO participant, that adversely impacts the RO participant's ability to deliver care in accordance with the RO Model's requirements, and that affects an entire region or locale. If CMS declares an EUC, CMS may do the following: 1) amend the model performance period, 2) eliminate or delay certain reporting requirements for RO participants, and/or 3) amend the RO Model's pricing methodology.
- **Legacy TIN:** A taxpayer identification number (TIN) for an RO participant that is a professional

group plan, a freestanding radiation therapy center, or its predecessor(s) previously used to bill Medicare for included radiotherapy (RT) services but no longer uses it to bill Medicare for included RT services.

- **Legacy CCN:** A CMS certification number for 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 the number to bill Medicare for included RT services.
- **Track one:** A track for professional participants and dual participants that meet all RO Model requirements set forth at §512.220, including use of CEHRT (certified EHR technology). RO Model participants in Track One will be considered to be participating in an advanced alternative payment model (APM) and the Merit-Based Incentive Payment System (MIPS) APM under the RO Model (updated for 2022).
- **Track two:** A track for professional participants and dual participants that meet all RO Model requirements set forth at §512.220, except for use of CEHRT (updated for 2022).
- **Track three:** A track for all technical participants and those professional participants and dual participants that do not meet one or more of the RO Model requirements set forth at § 512.220(a). For example, a professional participant or dual participant that does not adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate would be in track three (new for 2022).
- **Baseline period:** The three-CY period that begins on January 1, that is no fewer than 5 years but no more than 6 years prior to the start of the model performance period during which episodes must initiate in order to be used to calculate national base rates, participant-specific professional and technical historical experience adjustments for the model performance period, and participant-specific professional and technical case mix adjustments for PY1.
- **Model performance period:** The five PYs (performance years) during which RO episodes must initiate and terminate.
- **Performance year (PY):** This term was modified 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 the set date and end on December 31 of the same year.
- **Stop loss reconciliation amount:** The amount owed to RO participants who have fewer than 60 episodes during the baseline period and who were previously furnishing the included RT services before the start of the model performance period in the CBSAs (core-based statistical areas) that were selected for participation for the loss incurred under the RO Model as described in §512.285(f) (updated for 2022).

Random Selection of RO Participants

Providers were randomly selected from designated core-based statistical areas (CBSAs) as defined by the Office of Management and Budget. Providers and suppliers are linked to a CBSA by the 5-digit ZIP code that is reported on the claim form for where services were provided, as credentialed with CMS. Since many RT providers and suppliers may not know what CBSA their services are provided in and to ensure understanding of which providers are randomly selected, CMS published the list of ZIP codes that correlate to the randomly selected CBSAs on the RO Model website (innovation.cms.gov/innovation-models/radiation-oncology-model).

There are a few exclusions to the RO Model. Specifically, any physician practice groups, freestanding centers, or hospital outpatient departments that furnish radiation oncology services in or paid under the systems listed below are excluded, even if they are in a randomly selected CBSA. This exclusion is due to the potential overlap or interference in already established payment systems of reimbursement for radiation oncology services. Exclusions include:

- The state of Maryland: Excluded due to its statewide payment model.
- The state of Vermont: Excluded due to All-Payer ACO (Affordable Care Organization)
- U.S. territories: Excluded due to low volume of radiation oncology services provided
- Ambulatory surgical centers (ASCs): Excluded due to low volume of radiation oncology services provided
- Critical access hospitals (CAHs): Excluded due to differences in how CMS currently makes payments
- Prospective payment system (PPS)-exempt cancer hospitals: Excluded due to differences in how CMS currently makes payments.
- Hospital outpatient departments (HOPDs) actively participating in the Pennsylvania Rural Health Model: Excluded due to receiving payments under a different model; participants that stop participation in this model and that are in an eligible CBSA are then required to participate in the RO Model (updated for 2022).
- Community Health Access and Rural Transformation (CHART): CHART participants will be RO participants in PY1 of the RO Model and are only excluded once the CHART Community Transformation track model performance period begins (updated for 2022).

If the status or location of a provider or supplier changes during the time the RO Model is in effect, this may exclude or require participation. For example, if an RO participant were to move a location from a randomly selected CBSA to Maryland, the location would be excluded from the RO Model effective the date of the location change. This scenario would also be true if a location in Maryland moved to a randomly selected CBSA; the location would be required to participate as of the date of its location change. This scenario applies to physicians or physician groups, HOPDs, and/or freestanding cancer centers that move during the 5-year span of the RO Model as well as any entities whose status is changed from PPS-exempt.

Low Volume Opt Out

CMS previously finalized a low volume opt-out option for selected participants that is available annually. If a selected participant has provided fewer than 20 episodes of RT services in the most recent claims data available in one or more of the CBSAs selected to participate, prior to the applicable performance year, the participant may elect to opt-out of the PY.

CMS has removed any incentive for RO participants to change their TIN or CCN as a means to become eligible for the low volume opt-out option. An entity would not be eligible to opt out if its legacy TIN or legacy CCN was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services within the two years prior to the corresponding performance year in a selected CBSA. The agency will include episodes and RO episodes associated with the RO participant's current CCN or TIN, as well as any episodes and RO episodes attributed to the RO participant's legacy CCN(s) or TIN(s).

CMS will continue to notify participants 30 days prior to the start of the PY if they are eligible to opt out. The participant must then attest on or before December prior to the start of the next PY their intention to opt out.

Beneficiary Coinsurance

CMS did not make changes to the criteria for beneficiary eligibility. If there is an incomplete episode and the beneficiary no longer has traditional fee-for-service Medicare before all RT services are provided in the episode, payment would be reconciled to services provided professionally and technically using the no-pay claims. CMS would then pay for the services rendered as if these services were provided under FFS. The beneficiary would be responsible for their 20 percent coinsurance for the services provided using the rates of the FFS applicable amount.

RO Model Cancer Types

CMS has changed the number of cancer types included in the RO Model. Initially, services provided to a RO beneficiary during a 90-day episode of care for 16 cancer types were finalized. After consideration and stakeholder feedback, CMS removed liver diagnosis from the cancer types included. The agency indicated that liver cancer and the radiation therapy services used to treat this cancer are evolving. Various randomized clinical trials do not include radiation therapy as a first-line therapy. Due to this and other stakeholder feedback, CMS only included 15 cancer types in the RO Model. Any future cancer types added would still need to meet the criteria initially established:

1. All are commonly treated with radiation
2. Make up the majority of all incidences of cancer types
3. Have demonstrated pricing stability.

Table 1, page **XX** provides the updated ICD-10-CM codes included in the RO Model. CMS may add or change a diagnosis during the active RO Model period; communication will be provided through the RO Model website and written correspondence to RO participants. Any changes will be communicated per the standard process for changes by CMS no later than 30 days prior to each performance year (PY).

Assignment of Cancer Type to an Episode

CMS provided some language on how it will analyze and determine the episode's cancer type assignment according to an algorithm. The following is what CMS clarified as its process for determining the episode cancer type when there is a secondary diagnosis or multiple diagnoses.

1. If two or more claim lines fall within brain metastases, bone metastases, or secondary malignancies (per the mapping of ICD-10-CM diagnosis code to cancer type described in **Table X** of identified cancer types and corresponding ICD-10-CM codes), CMS will set the episode cancer type to the type (either brain metastases or bone metastases) with the highest count. If the count is tied, CMS will assign the episode in the following order of precedence: brain metastases; bone metastases; other secondary malignancies.
2. If there are fewer than two claim lines for brain metastases, bone metastases, or other secondary malignancies, CMS will assign the episode to the cancer type with the highest claim line count among all other cancer types. CMS will exclude the episode if the cancer type with the highest claims line count among other cancer types is not an included cancer type.
3. If there are no claim lines with a cancer diagnosis meeting the previously discussed criteria, then no cancer type is assigned to that episode and, therefore, that episode is excluded from national base rate calculations.

CMS also addressed that when there are not at least two claim lines for a diagnosis, like brain or bone metastases as outlined in the example above, it would then assign the episode the cancer type with the

highest line count among all other cancer types. In reviewing this verbiage, questions arose regarding how this will be carried out, specifically because the UB04 claim used by hospitals does not allow for use of a diagnosis pointer to identify which services belong to which diagnosis. This identification is only possible on the CMS1500 claim form. Therefore, clarification is needed from CMS to determine if the CMS1500 claim by the physician will always determine the cancer type assignment since pointers cannot be used on the UB04 claim by the hospital.

Included Radiation Therapy Services

CMS is not including evaluation and management (E/M) services within the RO Model, primarily due to the fact that these codes are used by multiple providers. Therefore, CMS did not include them in the list of covered services under the RO Model. CMS also excluded other services, such as neutron beam therapy, hyperthermia treatment, intraoperative radiotherapy (IORT), yttrium-90 courses, and radiopharmaceuticals.

CMS is removing brachytherapy services from the list of included radiation therapy services as part of the RO Model due to stakeholder feedback, which indicated that because of bundled payments there could be decreased utilization where combined external beam and brachytherapy would be clinically indicated, specifically for cervical and prostate cancers. There is belief that the bundling will ultimately result in the disincentive to refer patients to another radiation oncologist for treatment when the RO participant does not or cannot deliver brachytherapy services themselves. CMS addressed this issue by stating it does not seek to *“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 fact that brachytherapy is excluded does not speak to any lesser value it presents as a modality to treat patients. Published clinical evidence suggests this modality is highly valued and meets the criteria for inclusion; however, stakeholder concerns and the potential unintended consequences could have an impact, and CMS acknowledged this. CMS will continue to monitor brachytherapy utilization, both as a single and multi-modality for RO participants compared to non-participants.

CMS sought comments on whether IORT should be included in the RO Model. CMS received stakeholder feedback requesting the modality be added; however, due to the fact the modality is only performed in the hospital setting, it is not setting agnostic, and is limited to certain cancer types, CMS had concerns about its inclusion. Based on the criteria to be included in the RO Model, CMS does not believe the modality is appropriate for inclusion but sought comments on whether it should be considered. CMS did receive feedback and will consider the modality for future rulemaking but did not include it at this time.

The list of HCPCS codes considered bundled into the RO Model is available on RO Model website (innovation.cms.gov/innovation-models/radiation-oncology-model).

Pricing Methodology

To determine overall reimbursement, the pricing methodology of the RO Model applies eight primary steps to each cancer type:

- **Step 1.** CMS will create ***national base rates*** for the PC (professional component) and TC (technical component) of the included cancer types. With the selected 15 cancer types included in the Model, CMS would create 30 different base rates (15 for their PC and 15 for their TC). Rates would reflect a national historical average cost for each cancer type and episode of care as based on claims data from a three-year period.

- **Step 2.** CMS will gather ***trend factor accounts*** for current trends in payment for RT services and the volume of these same services provided outside the RO Model under HOPPS and MPFS. This will ensure the RO Model accurately reflects changes in treatment patterns and payment rates that have occurred under FFS. The actual number will vary and depend on the number of cancer types included in the RO Model. After CMS issues the annual HOPPS and MPFS final rules for the upcoming year, CMS will make these factors available on the RO Model website.
- **Step 3.** A ***geographic adjustment*** will be applied to national base rate payments. HOPDs would utilize the post-reclassification hospital wage index to 60 percent (labor-related share) of the HOPPS rate. For RO Model participants paid under the MPFS, CMS would create a set of RO Model specific relative value units (RVUs) for each HCPCS code of the included services. These values would be used to calculate the geographically adjusted payment amounts, as with other services paid under FFS, with work, practice expense, and malpractice RVUs.
- **Step 4.** CMS will adjust the national base rate to account for each RO Model participant's historical experience and case mix history which will be weighted by an efficiency factor. This would include one professional and/or one technical case mix adjustment and one historical experience per RO participant, depending on the type of component the RO participant furnished from CYs 2017 to 2019. CMS will calculate these values and provide them to each RO Model participant at least 30 days prior to the next PY. The equations will look something like this: case mix adjustment = (predicted payment minus expected payment) divided by expected payment; historical experience adjustment = (winsorized payments minus predicted payments) divided by expected payments
- **Step 5.** A ***discount factor*** will be applied to the national base rate. The discount factor is a set percentage by which CMS reduces the episode payment amount. It is applied after the trend factor and other previous adjustments are applied. CMS is adjusting the previously finalized discount factors. For CY 2022, CMS set a PC discount factor of 3.50 percent and a TC discount factor of 4.50 percent, a 0.25 percent reduction for each, respectively.
- **Step 6.** An ***incorrect payment withhold*** will be applied. CMS finalized a 1 percent withhold, applied for both PC and TC payments of each cancer type; a 2 percent withhold to PC payments as part of a quality withhold; and a 1 percent withhold beginning at performance year 3 (PY3) for TC payments related to the patient experience. There are essentially two withhold categories by CMS to potentially avert any incomplete episodes or duplicate billing for bundled services, which would result in incorrect payment, and a third withhold category related to the quality and patient experience.
- **Steps 7 and 8.** Adjustments of the RO beneficiary's 20 percent coinsurance would be applied as well as the sequestration, which is in effect at the time of the corresponding PY.

CMS finalized the national base rates and HCPCS codes for reporting professional and technical services. Table 2, page XX, lists the proposed PC and TC rates as well as the HCPCS codes used to identify the cancer type.

CMS will no longer reference the specific CY(s) from the definition baseline period. Instead, the agency will use the three-year span to determine the weighting, and rates will be based on the dates of service for the Medicare FFS claims paid during the baseline period and those under an episode where the initial clinical treatment planning occurred. CMS indicated that it would weigh more recent episodes more heavily in the baseline period than those earlier in the baseline period. For example, the first year of the 3-year baseline period would be weighted at 20 percent, episodes initiated in second year at 30 percent, and episodes initiated in the third year of baseline at 50 percent.

CMS will exclude any of the entities not part of the RO Model, those not in selected CBSAs, and any cancer types not selected to be part of the RO Model. The base rates would be based on the three-year calculation for services included.

Quality Measure Reporting for Professional and Dual Participants

Professional and dual participants will begin reporting quality measures in PY1. Both participants will be required to submit data for three pay-for performance measures:

1. **Quality ID #047 (NQF 0383):** Oncology: medical and radiation—plan of care for moderate to severe pain
2. **Quality ID #134 (NQF 0418):** Preventive Care and Screening: screening for depression and follow-up plan
3. **Quality ID #47 (NQF 0326):** Advance Care Plan

A fourth measure is also required to be reported, but it is a pay-for-reporting measure. The reporting from this measure will be used to propose a benchmark to re-specify it as a pay-for-performance measure for PY3. CMS did finalize that the agency will update the specifications of the following measure should new specifications from the measure's steward meet the RO Model's needs. Any updates will be communicated by CMS with any substantial changes made through a rulemaking and comment process.

1. Treatment Summary Communication: Radiation Oncology

As part of the RO Model, CMS will also be using the CAHPS® Cancer Care Survey to evaluate the RO beneficiary experience. Due to RO Model's timeline changes, the CMS-approved contractor will begin administering the CAHPS Cancer Care Radiation Therapy Survey on behalf of RO participants and CMS as soon as there are completed RO episodes, which will be no earlier than the fourth month of the model performance period.

Professional and dual participants must collect certain clinical information not available in claims or quality measures. Data was finalized to begin collection in PY1, and CMS finalized that professional and dual participants will submit clinical data elements starting PY1.

CMS expects the RO Model to meet the criteria to be an Advanced APM and MIPS APM in PY1, beginning January 1, 2022. Professional and dual participants that meet RO Model requirements will be either track one or track two. Professional and dual participants who do not meet one or more of the RO Model requirements and all technical participants will be considered track three (see definitions, page XX, for each). Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component will not be participating in track one or track two of the RO Model. Final CMS determinations of Advanced APMs and MIPS APMs for the 2022 performance period will be announced via the Quality Payment Program website at: qpp.cms.gov.

Extreme and Uncontrollable Circumstances Policy

There may be circumstances outside the control of RO Model participants related to pandemics, natural or other disasters, or other extraordinary circumstances. In these instances, CMS could institute the extreme and uncontrollable circumstances (EUC) policy allowing for modification of the RO Model for designated and impacted RO participants. To help identify RO participants that are experiencing an extreme and uncontrollable circumstance, CMS would consider the following factors:

- Whether RO Model 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 the geographic area within a county, parish, U.S. territory, or tribal government designated under the Stafford Act served as a condition precedent for the Secretary's exercise of the 1135 waiver authority or the National Emergencies 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 the EUC policy applies to one or more RO Model participants within an affected geographic area. CMS would communicate this decision via the RO Model website and written correspondence to RO participants. Geographic region(s) that are considered affected would be identified by state, county, or ZIP code, as is common for emergency declarations. CMS would then identify the affected participants by ZIP code, as is done to determine eligible Model participants. In those instances where the EUC policy was enacted impacting RO participants nationwide, such that it was a significant experience resulting in a trend factor that shifts more than 10 percent, either positive or negative, compared to previous values, CMS may modify the trend factor for the PC and/or TC of the included cancer type.

CMS has developed many additional resources, webinars, and tools that are available on the RO Model website (innovation.cms.gov/innovation-models/radiation-oncology-model). Providers should review these resources and register for the educational webinars.

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This information will be published in the January-February 2022 edition of Oncology Issues.

The Radiation Oncology Model Update is provided by the [ACCC Alternative Payment Model Coalition](#). Support provided by Merck & Co, Inc.

Table 1. Included Cancer Types and Corresponding ICD-10 Codes Included in the RO Model

Cancer Type	ICD-10 Codes
Anal cancer	C21.xx
Bladder cancer	C67.xx
Bone metastases	C79.5x
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

CNS = central nervous system; GI = gastrointestinal

Table 2. RO Model National Base Rates

RO Model-Specific HCPCS Codes	Professional or Technical	Included Cancer Type	National 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 and neck cancer	\$3,107.95
M1089	Technical	Head and 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

CNS = central nervous system; GI = gastrointestinal