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2022 HOPPS & RO MODEL PROPOSED RULE SUMMATION

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2022 HOPPS & RO Model Proposed Rule Summation

On July 19, 2021, the Centers for Medicare & Medicaid Services (CMS) proposed Medicare payment rates for hospital outpatient and Ambulatory Surgical Center (ASC) services, which includes proposals related to the Radiation Oncology (RO) Model.

Payments

In accordance with Medicare law, CMS is proposing to update OPPS payment rates for hospitals that meet applicable quality reporting requirements by 2.3 percent. CMS estimates that the total payments to hospitals for Calendar Year (CY) 2022 will be $82.704 billion which is an increase of $10.757 billion for estimated CY 2021.

CMS proposes to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

Brachytherapy Sources

CMS proposes to use the costs derived from CY 2019 claims data to set the proposed CY 2022 payment rates for brachytherapy sources. Two exceptions are for source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and brachytherapy source C2636 (Brachytherapy linear source, non-stranded, palladium-103, per 1 mm), which CMS proposes to base payment on the geometric mean unit costs for each source.

In addition, the stranded and non-stranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), are proposed to be at a rate equal to the lowest stranded or non-stranded prospective payment rate for such sources.

It is also proposed that CMS will set payment for new brachytherapy sources, for which they have no claims data with prospective payment rates set based on their consideration of external data and other relevant information regarding the expected costs of the sources to hospitals.

CMS is proposing to establish a Low Volume APC policy for New Technology APCs, clinical APCs, and brachytherapy APCs. These are APCs with fewer than 100 single claims in the existing claims year. CMS proposes to use up to four years of claims data to establish a payment rate for each item or service as they currently do for low volume services assigned to New Technology APCs. They will then calculate the cost for Low Volume APCs based on the greatest of the arithmetic mean cost, median cost, or geometric mean cost.

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There are 5 brachytherapy APCs that CMS wishes to consider as Low Volume APCs for CY 2022.

2632 Iodine I-125 sodium iodide
2635 Brachytx, non-str, HA, P-103
2636 Brachy linear, non1str, P-103
2645 Brachytx, non-str, Gold-198
2647 Brachytx, NS, Non1HDRIr-192

Cancer Hospitals

CMS is proposing adjustments to cancer hospitals. The actual amount of the CY 2022 cancer hospital payment adjustment will be determined at cost report settlement and will depend on each hospital's CY 2022 payments and costs.

ESTIMATED CY 2022 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2022 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	31.3%
050660	USC Norris Cancer Hospital	9.9%
100079	Sylvester Comprehensive Cancer Center	16.5%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.8%
220162	Dana-Farber Cancer Institute	34.3%
330154	Memorial Sloan-Kettering Cancer Center	38.1%
330354	Roswell Park Cancer Center	14.0%
360242	James Cancer Hospital & Solove Research Institute	16.4%
390196	Fox Chase Cancer Center	11.2%
450076	M.D. Anderson Cancer Center	51.4%
500138	Seattle Cancer Care Alliance	46.5%

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RO MODEL

In September 2020, the Center for Medicare and Medicaid Innovation (the Innovation Center) published a final rule that established the Radiation Oncology (RO) Model with a start date of January 1, 2021. As a result of the ongoing COVID-19 PHE, CMS included an interim final rule with comment period (IFC) in the CY 2021 OPPS/ASC Final Rule to delay the start of the RO Model until July 1, 2021. Subsequently, the Consolidated Appropriations Act, 2021, included a provision that prohibits implementation of the RO Model prior to January 1, 2022, effectively delaying the start date by at least 6 months.

HIGHLIGHTS

The CY 2022 OPPS and ASC Payment System proposed rule includes the following proposals to modify the RO Model's timing and design:

- To begin the RO Model on January 1, 2022, with a 5-year Model performance period (ending December 31, 2026).
  - No episodes may begin after Oct. 3, 2026, in order for all episodes to end by Dec. 31, 2026
- To change the baseline period from 2016-2018 to 2017-2019, unless the RO Model is prohibited to start by law in which case the baseline period would change. This baseline period is what determines the calculation for the national base rates, the historical experience adjustments, and the case mix adjustments.
- To lower the discounts to 3.5 percent (Professional Component) and 4.5 percent (Technical Component).
- To remove brachytherapy from the list of included modalities under the RO Model so that it would still be paid FFS. There were many stakeholder comments regarding the concern that some patients would not be referred from one radiation oncologist that does not delivery brachytherapy to another to another radiation oncologist that does perform brachytherapy. In addition, there was concern that there would be decreased utilization of brachytherapy for cases where external beam and brachytherapy are clinically indicated. CMS states that if brachytherapy is removed, they are requesting information on how payments for multi-modality care might be handled in the future.
- To revise the cancer inclusion criteria under the RO Model.
- Low Volume Optout – CMS is proposing in this rule to clarify the type of episodes used to determine the low volume opt out in each performance year. A RO model participant may choose to opt out if for a given PY it has fewer than 20 RO episodes in the 2 years prior to the applicable PY. CMS clarified that if a legacy TIN or legacy CCN was used to bill more than 20 episodes, then the entity would not qualify for the low volume opt out. CMS further stated they are proposing this rule to remove any incentive for an RO Model participant to change their TIN or CCN.
- In cases where a beneficiary switches from traditional Medicare to Medicare Advantage during an episode before treatment is complete, CMS would consider this an incomplete episode and RT services would be paid the traditional Medicare rate instead of being paid under the RO Model.
- To adopt an extreme and uncontrollable circumstances policy. This policy would provide flexibility to reduce administrative burden of Model participation, including reporting

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requirements, and/or adjust the payment methodology as necessary when extreme and uncontrollable circumstances exist.

- To exclude hospital outpatient departments participating in the Community Transformation track of the CHART Model from participation in the RO Model. For the CHART ACO Transformation track, CMS would follow the same policy for overlap between the RO Model and the Medicare Shared Savings Program ACOs.
- That only hospital outpatient departments that are participating in the Pennsylvania Rural Health Model (PARHM) would be excluded from the RO Model, rather than those that are eligible to participate in PARHM.
- To remove liver cancer from the RO Model as it does not satisfy the model's cancer inclusion criteria.

Pricing Methodology for the RO Model

1. **Assignment of Cancer Types to an Episode**

Identified Cancer Types and Corresponding 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

2. **Proposal to Construct Episodes Using Medicare FFS Claims and Calculation of Episode Payment**

CMS proposed that they construct 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 they are removing references to specific CYs, they will continue to weigh the most recent observations more heavily than those that occurred in earlier years, as previously finalized. CMS would continue to weigh episodes that initiated in the first year of the baseline period at 20 percent, episodes that initiated in second year of the baseline period at 30 percent, and episodes that initiated in the third year of the baseline period at 50 percent.

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CMS is also proposing that sequestration be applied in accordance to the law versus their previous statements.

CMS is inviting the public comment on this proposal to weigh the most recent episodes more heavily than those that occurred in earlier years in the baseline period and on the sequestration proposal.

3. Proposed National Base Rates

National Base Rates

RO Model-Specific Codes	Professional or Technical	Included Cancer Types	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 Metastasis	$1,446.41
M1077	Technical	Bone Metastasis	$6,194.22
M1078	Professional	Brain Metastasis	$1,651.56
M1079	Technical	Brain Metastasis	$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

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4. Proposed Trend Factors

a. CMS is clarifying that the number of separate trend factors will vary depending on the number of cancer types included in the RO Model. Further, given the delay in the model performance period and proposal to update the baseline period, CMS is proposing that the numerator of the trend factor be the product of (a) the component's FFS payment rate (as paid under OPPS or PFS) for the 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 3 years prior to the CY used to determine the FFS payment rates.
b. In addition, CMS is proposing the denominator of the trend factor 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. For example, for PY1, they would calculate the trend factor as: 2022 Trend factor = (2019 volume * 2022 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS). As another example, for PY3, they would calculate the trend factor as: 2024 Trend factor = (2021 volume * 2024 corresponding FFS rates as paid under OPPS or PFS)/(2019 volume * 2019 corresponding FFS rates as paid under OPPS or PFS).
c. The trended national base rates will be made available on the RO Model website prior to the start of the applicable PY, after CMS issues the annual OPPS and PFS final rules that establish payment rates for the upcoming CY

5. Applying the Adjustments

CMS previously finalized that the combined adjustment, that is the adjustment that results when the corresponding participant-specific historical experience and case mix adjustments, and blend are combined, be multiplied by the corresponding trended national base rate for each cancer type. 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.

6. Proposal for HOPD or Freestanding Radiation Therapy Center with Fewer Than Sixty Episodes During the Baseline Period

CMS had finalized a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes from 2016 through 2018 and were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of Specialty Care Models Rule. Under this 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 under the stop-loss policy

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would be determined at the time of reconciliation. CMS is inviting public comments on the proposal that the stop-loss limit policy would apply to RO participants that have fewer than 60 episodes during the proposed 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.

7. **Proposal to Apply Adjustments for HOPD or Freestanding Radiation Therapy Center With a Merger, Acquisition, or Other New Business Relationship, With a CCN or TIN Change**

CMS had finalized those entities required to participate in the RO Model, and an entity must participate in the RO Model if it has a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025, begins to furnish RT services within a CBSA selected for participation, and meets the RO Model's eligibility requirements. They 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. In addition, they finalized that RO participants must also provide a notification regarding a new clinical relationship that may or may not constitute a change in control, and if there were sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN.

CMS is now proposing that they would calculate 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 3-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 3-year period that determines the case mix adjustment for each PY. They also propose to calculate the RO participant's historical experience adjustments in accordance 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. CMS will require an RO participant to furnish to them a 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.

8. **Proposed Discount Factor**

CMS proposes to lower the discount factor for the PC to 3.5 percent and the discount factor for the TC to 4.5 percent. This hinges on both brachytherapy and liver cancer being removed from the RO Model, only if these two items are finalized will the discount factor be lowered.

9. **Proposed Withholds**

In this proposed rule, CMS is proposing that RO participants submit quality measure data starting in PY1 (when the model performance period begins) and that beginning in PY1, a 2 percent quality withhold for the PC would be applied to the applicable trended national base

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rates after the case mix and historical experience adjustments.

10. Proposed Adjustment for Geography

CMS previously described in RO Model that the RO Model-specific relative value unit (RVU) values would be derived from the national base rates which are based on 2016 to 2018 episodes that had the majority of radiation treatment services furnished at an HOPD and that were attributed to an HOPD. They would use only 2018 episodes to calculate the implied RVU shares. CMS is now proposing to modify this provision to align with the proposed model performance period so that the final year of the baseline period would be used to calculate the implied RVU shares. For example, for a baseline period of 2017-2019, 2019 would be used to calculate the implied RVU shares.

Pages 709 & 710 of the Proposed Rule provides the reader with examples of both a professional and technical episodic payment.

CMS is 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 of this proposed rule, 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. However, they are 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 – Proposed Form, Manner, and Timing for Quality Reporting

CMS is proposing that Professional participants and Dual participants submit quality measure data starting in PY1 during the proposed model performance period. Under this proposal, if the proposed model performance period starts mid-year, the CY collection period would remain. For example, if the model performance period starts in July, RO participants would collect quality measure data for that CY starting in January. This would allow RO participants to use their MIPS data submission to meet the RO Model requirements.

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 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 substantive changes to measure specifications would be addressed through notice and comment

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CMS also previously finalized that a CMS-approved contractor would administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Survey for Radiation Therapy, beginning in October 2021. Given the change in model performance period due to the delay under section 133 of the CAA 2021, CMS is proposing that they amend the existing policy such that the CMS-approved contractor will begin administering the CAHPS® Cancer Care Survey for Radiation Therapy on behalf of the RO participants and CMS as soon as there are completed RO episodes, no earlier than the fourth month of the model performance period.

In this proposed rule, CMS is proposing that Professional participants and Dual participants submit CDEs starting in PY1.

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

Despite the delay, CMS expects the RO Model to meet the criteria to be an Advanced APM and a MIPS APM beginning in PY1, beginning January 1, 2022. 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/.

Criteria to be an Advanced APM are:

- CEHRT usage. 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.
- Payment based on quality measures. This criterion is satisfied because payment under the RO Model is based on MIPS-comparable quality measures. Specifically, the RO participant will have their payment amount adjusted by the 2 percent quality withhold with the chance of earning back some or all of that amount back.
- Financial Risk. This criterion is satisfied by the application of the discount factor to RO Model payments, the application of the quality withhold to the RO Model payments, and the fact that RO participants are responsible for 100 percent of all expenditures in excess of the expected amount of expenditures beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment, with the exception of those RO participants that qualify for the stop-loss policy.

CMS clarified that Professional participants and Dual participants who meet the RO Model requirements, including use of CEHRT, and who are eligible clinicians on a Participation List, will fall into a category called "Track One" of the RO Model. CMS proposes to define "Track One" to mean an Advanced APM and MIPS APM track for Dual participants and Professional participants that use CEHRT.

If eligible clinicians who are Track One RO Participants do not meet the thresholds to become QPs, they will be considered to be participating in a MIPS APM and can report to MIPS using reporting options applicable to MIPS APM participants. At the start of a PY, if Professional participants or Dual

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participants fail to meet any of the RO Model requirements, which includes use of CEHRT, they will be moved into a separate category called "Track Two" of the RO Model for that PY. CMS is proposing to define "Track Two" to mean an APM for Dual participants and Professional participants who do not meet the RO Model requirements, and for all Technical participants. RO participants that fall into Track Two will not be participating in an Advanced APM or MIPS APM for the RO Model. As such, CMS will not make QP determinations for the eligible clinicians on the RO Model Participation List for Track Two. If an RO participant meets the CEHRT use requirements by the last QP determination snapshot date specified they will be moved to Track One of the RO Model and considered at that point to be participating in an Advanced APM, provided the RO participant meets all other RO Model requirements. Other RO Model requirements are: requirements to discuss goals of care and RO Model cost-sharing responsibilities with each RO beneficiary; adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate; assess each RO beneficiary's tumor, note, and metastasis cancer stage; and send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of the treatment.

Under this proposal, any failure to comply with the requirements will result in Track Two status for the RO participant and would be subject to remedial action. CMS does recognize that an RO participant's noncompliance with the terms might not be discovered until after CMS has treated the RO participant as if they were in Track One, including potentially making QP determinations for an RO participant's eligible clinicians and making APM Incentive Payments. In that event, the payments CMS would make based on the QP status of the RO participant's eligible clinicians pursuant to its Track One status would constitute overpayments. CMS is concerned that, in the case of minor noncompliance with the requirements, such overpayment liability may be too harsh. CMS is considering removing the requirement that RO Model participants must meet all of the requirements to remain in Track One so they are considering whether the final rule should modify some of the requirements. For example, instead of requiring certain actions for "each RO beneficiary," CMS is considering whether to require those actions for a majority of RO beneficiaries or substantially all RO beneficiaries. In addition, they are considering whether the final rule should modify certain requirements to permit payment of some or all of the payments made based on the QP status of the RO participant's eligible clinicians pursuant to its Track One participation, depending on the severity of noncompliance and other factors. Again, CMS is looking for comments from stakeholders.

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 fall into Track Two of the RO Model. Technical participants will not be considered to be participating 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 is proposing that if the 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 addition, 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. CMS will monitor these RO participants for compliance with the requirement to report quality measures if they begin providing the professional component.

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Reconciliation Process

Reconciliation is the process to calculate reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services. With the delay in the RO Model CMS is now proposing that the quality reconciliation payment amount will apply to all PYs.

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 RO episodes initiated in the applicable PY. CMS previously stated that they would conduct the PY1 true-up reconciliation as early as August 2023, and the PY2 true-up reconciliation as early as August 2024, and so forth. Given the proposed change in model performance period due to the delay, CMS now 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, they would conduct the true-up reconciliation as early as August of PY3.

Proposed Reconciliation Amount Calculation - CMS had finalized that a subset of incomplete episodes in which (1) the TC is not initiated within 28 days following the PC; (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC; or (3) the RO beneficiary switches RT provider or RT supplier before all RT services in the RO episode have been furnished, the RO participant would be owed only what it would have received under FFS for the RT services furnished to that RO beneficiary. CMS would reconcile the episode payment for the PC and TC that was paid to the RO participant with what the FFS payments would have been for those RT services using no-pay claims. Furthermore, CMS finalized in the case that traditional Medicare ceases to be the primary payer for an RO beneficiary after the TC of the RO episode has been initiated but before all included RT services in the RO episode have been furnished, each RO participant would be paid only the first installment of the episode payment. The RO participant would not be paid the EOE PC or TC for these RO episodes. CMS is proposing to modify 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.

Extreme and Uncontrollable Circumstance

CMS proposes to define 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. To help identify RO participants that are experiencing an extreme and uncontrollable circumstance, CMS would consider the following factors: • 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 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 extreme and uncontrollable circumstances policy applies to one or more RO participants within an affected geographic area. CMS would communicate this decision via the RO Model website and written correspondence to RO participants.

IMPACT OF RO MODEL ON CMS & PARTICPANTS

CMS currently 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. The RO Model will encompass 30% of all eligible RO episodes.

CMS now estimates with the revised baseline period, the removal of brachytherapy and liver cancer, as well as the lowered discounts, the savings to Medicare to be $160 million from the RO Model.

CMS believes that the proposed changes will not affect the total cost of learning the billing system for the RO Model but will, however, affect the burden estimate for reporting quality measures and clinical data elements. The burden estimate for collecting and reporting quality measures and clinical data for the RO Model may be equal to or less than that for small businesses, which CMS estimates to be approximately $1,845 per entity per year based on 2020 wages. Since they estimate approximately 500 Professional participants and Dual participants will be collecting and reporting this data, the total annual burden estimate for collecting and reporting quality measures and clinical data is approximately $922,500 for a total of $4,612,500 over 5 years.

Radiation Oncology Model PGP vs HOPD Allowed Charge Impacts 2022 to 2026

% Impact	2022	2023	2024	2025	2026	2022 to 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%

For more information on the RO Model, visit: https://innovation.cms.gov/initiatives/radiation-oncology-model/
RO Model, contact RadiationTherapy@cms.hhs.gov or at 844-711-2664, Option 5

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You are encouraged to comment regarding these proposed changes. Comments, including mass comment submissions, must be submitted in one of the following three ways:

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the “submit a comment” tab.
2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1753-P, P.O. Box 8010, Baltimore, MD 21244-1850.
3. By express or overnight mail. You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1753-P, Mail Stop C4-26-05,7500 Security Boulevard, Baltimore, MD 21244-1850