CY 2022 Final Rules Radiation Oncology
Hospital Outpatient Prospective Payment System (HOPPS)
November 8, 2021

On November 2, 2021, the Centers for Medicare and Medicaid Services (CMS) issued the final rule for the Hospital Outpatient Prospective Payment System (HOPPS) for CY 2022.

HOPPS Final Rule

The CY 2022 final rule is 1394 pages in length and located in its entirety at the following link: https://www.federalregister.gov/public-inspection/2021-24011/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-payment. The format of the following information is intended to serve as a summary to the finalized changes and readers are encouraged to view the document in its entirety for further details.

Highlights of Final Changes

- CMS finalized a 2.0 percent increase to the Outpatient Department (OPD) fee schedule. This is based on the proposed market update from the Inpatient Prospective Payment System (IPPS) of 2.7 percent and a minus 0.7 percent productivity adjustment.
    - CMS estimates total payments to HOPPS providers will be approximately $82.078 billion, an increase of approximately $5.913 billion compared to CY 2021 HOPPS payments.
    - CMS finalized maintenance of the policy to implement a wage index of 1.0000 for frontier states.
    - CMS will continue to use code G0463 (clinic visit) as the base code for establishing ambulatory payment classification (APC) for services paid under HOPPS.
        - CMS will also continue to pay code G0463 at 40 percent of the hospital outpatient rate when billed in the excepted and nonexcepted provider-based department of the hospital.
    - CMS finalized an increase of 2.0 percent to payment rates for ambulatory surgical centers (ASCs). CMS is anticipating a $20 million decrease in payments to ASCs for CY 2022.
- CMS will continue to apply a 2 percent reduction to the conversion factor for hospitals that fail to meet the hospital quality reporting requirements.
- Due to the impact related to the COVID-19 public health emergency (PHE) and pandemic, CMS used CY 2019 claims data for ratesetting rather than CY 2020 due to significant impact in utilization of services.
- CMS proposed and finalized to re-adopt the ASC Covered Procedures List (CPL) that was in effect in CY 2020. After review of recommendations, six procedures were determined to remain or be added to the CPL. CMS also finalized to change the notification process adopted for CY 2021 to a nomination process, allowing stakeholders to nominate procedures they believe meet the criteria to be included on the list.
- CMS proposed and finalized exceptions to 23 APCs under the 2 times rule violation. Typically, codes within the APCs violating this rule would need to be moved or a new APC created, CMS will allow the classifications to continue as is.

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- CMS sought comments on the proposal to establish the CY 2022 device offset percentage using CY 2019 claims data when there is no data from CY 2020 for device intensive procedures. There are 11 procedures this would impact, specifically HCPCS C9757, C9765, and C9767.
    - CMS proposed and finalized to continue recognition of HCPCS C1889 for billing of the device as part of a device intensive procedure when there is no specific Level II HCPCS Category C-code to represent it.
- CMS will continue the additional payments to the 11 designated cancer hospitals. The adjustment, a payment-to-cost ratio (PCR) of 0.90, is applied at the cost report settlement for each cancer hospital, this is an increase from CY 2021.
- CMS proposed and finalized creation of low-volume APCs for designated clinical, brachytherapy, and new technology services. These would be APCs with fewer than 100 single claims in the year used for ratesetting for clinical and brachytherapy APCs.
    - Brachytherapy APCs 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) would not be included in this payment process. These non-specific APCs already have an established method for determining pricing.
    - CMS will designate five brachytherapy APCs as low volume. Payment rates used claims data from a 4-year span, 2016 -2019.
        - The five brachytherapy APCs are 2632 (Iodine I-125 sodium iodide), 2635 (Brachytx, non-str, HA, P-103), 2636 (Brachy linear, nonstr, P-103), 2645 (Brachytx, non-str, Gold-198), and 2647 (Brachytx, NS, Non-HDRIr-192).
- CMS sought comments on several waivers and extensions as part of the PHE for COVID-19. They also sought comments as to whether services can continue through telehealth to beneficiaries in their homes, direct supervision for certain designated services by real time audio/video capabilities, and code and payment for COVID-19 testing. At this time CMS is considering comments submitted for future rulemaking with some extensions continuing for mental health services specifically.
- CMS finalized, unless prohibited by law, to implement effective January 1, 2022 – December 31, 2026, the Radiation Oncology (RO) Payment Model. CMS finalized several updates to the RO Model including the removal of liver diagnosis as one of the cancer types and removal of brachytherapy services from the list paid under the RO Model.

Payment Rates

Due to the impact related to the COVID-19 public health emergency (PHE) and pandemic, CMS used CY 2019 claims data for ratesetting rather than CY 2020 due to significant impact in utilization of services. Based on this, CMS finalized a 2.0 percent increase to the Outpatient Department (OPD) fee schedule. This is based on the proposed market update from the Inpatient Prospective Payment System (IPPS) of 2.7 percent and a minus 0.7 percent productivity adjustment. CMS used a conversion factor (CF) of $84.177 for hospitals meeting the reporting criteria and applying the 2 percent reduction to those that do not. CMS estimates total payments to HOPPS providers will be approximately $82.078 billion, an increase of approximately $5.913 billion compared to CY 2021 HOPPS payments.

Wage Index

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CMS will continue applying a wage index of 1.0000 for frontier state hospitals, this policy has been in place since CY 2011. This ensures the lower population states are not "penalized" for reimbursement due to the low number of people per square mile when compared to other states.

Reimbursement

Using the finalized payment information, the following are examples of common services provided and payment amounts are based upon the published Medicare allowable for the CPT®/HCPCS codes in an on-campus hospital outpatient department specific to radiation oncology.

2021-2022 Final HOPPS Radiation Oncology Course Estimated Impacts

Type	HOPPS 2021 Course Medicare Allowable	HOPPS 2022 Course Medicare Allowable	2021-2022 Variance	2021-2022 % Change
2D - 10 fxs	$4,609.55	$4,708.07	$98.52	2.14%
3D - w/ imaging (33 fxs)	$13,622.23	$13,914.54	$292.31	2.15%
IMRT - Simple 44 fxs	$29,729.72	$30,364.54	$634.82	2.14%
IMRT - Complex 30 fxs	$20,484.71	$20,922.19	$437.48	2.14%
SRS- Linac	$9,987.35	$10,205.53	$218.18	2.18%
SRS- Cobalt (Same Day)	$9,648.67	$9,859.68	$211.01	2.19%
SRS- Cobalt Frameless	$9,987.35	$10,205.53	$218.18	2.18%
SBRT Linac 5 Fractions Cranial	$16,856.13	$17,218.52	$362.39	2.15%
SBRT - Cobalt 5 Fractions	$16,517.45	$16,872.67	$355.22	2.15%
Proton - 25 Fractions	$35,598.24	$36,246.12	$647.88	1.82%
Prostate - HDR	$10,827.85	$11,054.13	$226.28	2.09%
Prostate - LDR	$10,142.59	$10,356.60	$214.01	2.11%
GYN - T&O - HDR	$24,382.44	$24,901.52	$519.08	2.13%
GYN - Cylinder 1 Chan- HDR	$5,946.89	$6,077.90	$131.01	2.20%
GYN - Cylinder Multi Chan - HDR	$5,946.89	$6,077.90	$131.01	2.20%
APBI Single Channel - HDR	$16,517.45	$16,872.67	$355.22	2.15%
Skin Single Channel - HDR	$7,609.83	$7,771.43	$161.60	2.12%

Cancer Hospital Payment Adjustment

CMS will continue for CY 2022 the additional payments to cancer hospitals utilizing a payment-to-cost ratio (PCR) factor. Beginning in CY 2018, the 21st Century Cures Act required the weighted average PCR be reduced by 1.0 percentage point. CMS finalized the target PCR of 0.90, an increase from the proposed value, to determine the CY 2022 cancer hospital payment adjustment to be paid at cost report settlement, which includes the 1.0 percent reduction. Table 6 reflects the 11 designated cancer hospitals and the estimated payment adjustments for CY 2022.

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TABLE 6: 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	39.6%
050660	USC Norris Cancer Hospital	31.7%
100079	Sylvester Comprehensive Cancer Center	16.5%
100271	H. Lee Moffitt Cancer Center & Research Institute	20.8%
220162	Dana-Farber Cancer Institute	34.7%
330154	Memorial Sloan-Kettering Cancer Center	38.1%
330354	Roswell Park Cancer Institute	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%

Standardizing Ambulatory Payment Classifications (APCs) Payment Weights

Ambulatory payment classifications (APCs) group services which are considered clinically comparable to each other with respect to the resources utilized and the associated costs. CMS will continue using HCPCS code G0463, hospital outpatient clinic visit for assessment and management of a patient, in APC 5012 (Level 2 Examinations and Related Services) as the standardized code for the relative payment weights. A relative payment weight of 1.00 was assigned to APC 5012 (code G0463).

For CY 2022, CMS will continue to pay code G0463 at a payment rate of 40 percent of the HOPPS rate for any outpatient off-campus hospital setting, excepted and nonexcepted.

Ambulatory Payment Classification Updates CY 2022

All services (codes) associated with an APC are paid the exact same amount. If the resources and cost of services changes enough that the code with the highest cost of resources within an APC is more than 2 times that of the code with the lowest cost, CMS must adjust the placement of codes. This would be considered a 2 times rule violation and to correct it, codes would need to be moved to other APCs which better match resource cost or create a new APC for identified services.

Over the past few years, CMS has been providing an exception to the identified 2 times rule violation. The belief is many will work themselves out in the next claims data period with more accurate reporting. CMS identified 23 APCs with 2 times rule violations and will allow for exceptions to the following APCs.

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TABLE 10: CY 2022 APC EXCEPTIONS TO THE 2 TIMES RULE	
CY 2022 APC	**CY 2022 APC Title**
5051	Level 1 Skin Procedures
5055	Level 5 Skin Procedures
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5101	Level 1 Strapping and Cast Application
5112	Level 2 Musculoskeletal Procedures
5161	Level 1 ENT Procedures
5301	Level 1 Upper GI Procedures
5311	Level 1 Lower GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5571	Level 1 Imaging with Contrast
5593	Level 3 Nuclear Medicine and Related Services
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5673	Level 3 Pathology
5691	Level 1 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5821	Level 1 Health and Behavior Services
5823	Level 3 Health and Behavior Services

Multiple Imaging Composite APC

CMS will continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. Standard APC assignments will continue to apply for single imaging procedures and multiple imaging procedures performed across imaging families. A single imaging session performed "with contrast" is part of a composite APC when at least one or more imaging procedures from the same family are also performed with contrast on the same date of service. For example, if a hospital performs one MRI without contrast during the same session as one with, the payment rate will be for the "with contrast" composite APC.

The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

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Table 3 within the CY 2022 HOPPS final rule contains the imaging families and multiple imaging procedures for the composite APCs.

Brachytherapy Sources

CMS did not propose any significant changes to how reimbursement for brachytherapy sources is calculated. CMS did propose and finalize to use costs derived from CY 2019 claims data to set the CY 2022 payment rates and base the payment rates for brachytherapy sources on the geometric mean unit costs for each source. Brachytherapy sources, unless otherwise noted, are assigned status indicator (SI) "U." Codes with SI "U" are not packaged into C-APCs; the sources are paid separately in addition to the brachytherapy insertion code in the hospital setting.

CMS will continue to pay for the stranded and nonstranded not otherwise specified (NOS) HCPCS codes C2698 and C2699, at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per source basis (as opposed to, for example, a per mCi).

CMS invites submission of recommendations for new codes to describe new brachytherapy sources. These can be directed to the email address outpatientpps@cms.hhs.gov or by mail to the Division of Outpatient Care, Mail Stop C4 – 01 –26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244.

The following table reflects the estimated comparison of national payments by Medicare for a sampling of brachytherapy sources in the on-campus outpatient hospital setting.

HCPCS Code	Short Descriptor	2022 APC	2021 National Final Payment Rate	2022 National Proposed Payment Rate	Variance	% Change
A9513	Lutetium lu 177 dotatat ther	9067	$ 266.59	$ 274.33	$ 7.74	2.9%
A9606	Radium ra223 dichloride ther	1745	$ 140.96	$ 145.65	$ 4.69	3.3%
C1717	Brachytx, non-str,hdr ir-192	2646	$ 334.69	$ 341.72	$ 7.03	2.1%
C2616	Brachytx, non-str,yttrium-90	2616	$ 17,397.64	$ 17,763.21	$ 365.57	2.1%
C2634	Brachytx, non-str, ha, i-125	2634	$ 148.09	$ 151.20	$ 3.11	2.1%
C2635	Brachytx, non-str, ha, p-103	2635	$ 45.55	$ 45.62	$ 0.07	0.2%
C2636	Brachy linear, non-str,p-103	2636	$ 31.40	$ 52.57	$ 21.17	67.4%
C2638	Brachytx, stranded, i-125	2638	$ 37.40	$ 38.19	$ 0.79	2.1%
C2639	Brachytx, non-stranded,i-125	2639	$ 34.10	$ 34.82	$ 0.72	2.1%
C2640	Brachytx, stranded, p-103	2640	$ 87.75	$ 89.59	$ 1.84	2.1%
C2641	Brachytx, non-stranded,p-103	2641	$ 69.50	$ 70.95	$ 1.45	2.1%
C2642	Brachytx, stranded, c-131	2642	$ 71.86	$ 73.37	$ 1.51	2.1%
C2643	Brachytx, non-stranded,c-131	2643	$ 80.35	$ 82.03	$ 1.68	2.1%
C2645	Brachytx planar, p-103	2648	$ 4.69	$ 4.69	$ -	0.0%
C2698	Brachytx, stranded, nos	2698	$ 37.40	$ 38.19	$ 0.79	2.1%
C2699	Brachytx, non-stranded, nos	2699	$ 31.40	$ 34.82	$ 3.42	10.9%

CMS also proposed and finalized creation of low-volume APCs for designated clinical, brachytherapy, and new technology services. These would be APCs with fewer than 100 single claims in the year used for ratesetting for clinical and brachytherapy APCs. As stated previously, brachytherapy APCs 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) would not be included in this payment process. These non-specific APCs already have an established method for determining pricing.

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Instead, CMS will designate five brachytherapy APCs as low volume. Payment rates will use claims data from a 4-year span, 2016 -2019. The five brachytherapy APCs are 2632 (Iodine I-125 sodium iodide), 2635 (Brachytx, non-str, HA, P-103), 2636 (Brachy linear, nonstr, P-103), 2645 (Brachytx, non-str, Gold-198), and 2647 (Brachytx, NS, Non-HDRIr-192).

Device Intensive Procedures

CMS sought comments on the proposal to establish the CY 2022 device offset percentage using CY 2019 claims data when there is no data from CY 2020 for device intensive procedures. Device intensive status is assigned to procedures when the device cost exceeds a threshold of 40 percent related to the APC, then the status is awarded.

After reviewing comments, CMS finalized to use CY 2019 claims data for 11 procedures, three of them included in the list may be impactful to interventional radiology departments and should be noted for specific billing guidelines.

- C9757 *(Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and excision of herniated intervertebral disc, and repair of annular defect with implantation of bone anchored annular closure device, including annular defect measurement, alignment and sizing assessment, and image guidance; 1 interspace, lumbar);*
- C9765 *(Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy, and transluminal stent placement(s), includes angioplasty within the same vessel(s), when performed);* and
- C9767 *(Revascularization, endovascular, open or percutaneous, lower extremity artery(ies), except tibial/peroneal; with intravascular lithotripsy and transluminal stent placement(s), and atherectomy, includes angioplasty within the same vessel(s), when performed).*

CMS will continue recognition of HCPCS C1889 *(Implantable/insertable device, not otherwise classified)* for billing of the device as part of a device intensive procedure when there is no specific Level II HCPCS Category C-code to represent it.

Payment for Therapeutic Radiopharmaceuticals

New drugs, biologicals and radiopharmaceuticals are granted pass-through status by Medicare as a means of establishing a transitional payment until enough data is acquired to determine if the new agent is to be paid separately or packaged into an APC. For CY 2022, CMS will continue providing payment for diagnostic and therapeutic radiopharmaceuticals granted pass-through payment status based on average sales priced (ASP) methodology, as CMS considers these to be drugs under HOPPS. The ASP methodology is the ASP +6 percent; however, if no ASP data is available, CMS will continue to provide pass-through payment at wholesale acquisition cost (WAC) of +3 percent. If that is not available, then payment will be 95 percent of average wholesale price (AWP). CMS will also continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2022.

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Radiation Oncology (RO) Model

The following summary outlines the highlights and/or changes by CMS related to the Radiation Oncology (RO) Model, this includes some graphics from the proposed rule as they were not included in the final rule. All of the intricacies of the RO Model are not summarized here. CMS has created a RO Model website where additional resources and information can be accessed.

Due to the episodic nature of radiation oncology courses of treatment, CMS continues to believe radiation oncology is better suited for a payment model. The premise for 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, physicians and physician group practices, hospitals and freestanding centers. The results will allow for promotion of quality and financial accountability for episodes of care for radiation oncology services and ultimately reduce Medicare spending for their beneficiaries treated with radiation.

Payments will be site-neutral, meaning the same amount is paid regardless if performed in a hospital outpatient department (HOPD) or freestanding center. This will provide greater predictability of payments and manage the episode clinically rather than driven by fee-for-service (FFS) payments and incentives. The differences, as currently exist, in the payment systems under the HOPPS and Medicare Physician Fee Schedule (MPFS) would not exist in the RO Model.

Timeline of RO Model

Since the initial final rule detailing the timeline for the RO Model there have been several start date changes. Originally scheduled to start January 1, 2021, it 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 start prior to January 1, 2022.

Per the HOPPS CY 2022 final rule, the RO Model will begin January 1, 2022 and run through December 31, 2026. As CMS indicated, this is pending no legal or additional Congressional intervention. CMS also indicated no episodes of care could begin after October 3, 2026, to allow for completion prior to the scheduled end date on December 31st of that year.

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 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 CMS may do the following:
    - Amend the model performance period;
    - Eliminate or delay certain reporting requirements for RO participants; and
    - Amend the RO Model's pricing methodology.
- **Legacy TIN –** a taxpayer identification number (TIN) that an RO participant that is a professional group plan (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.

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- **Legacy CCN –** a CMS certification number (CCN) that an RO participant that is a hospital outpatient department (HOPD) or its predecessor(s) previously used to bill Medicare for included radiotherapy (RT) services but no longer uses 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. RO Model participants in Track One will be considered to be participating in an Advanced APM and 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. That is, a Dual participant or Professional participant who does not use CEHRT but meets all other RO Model requirements set forth at § 512.220 would be in Track Two. – **updated for 2022**
- **Track Three –** a track for Professional participants and Dual participants who do not meet one or more of the RO Model requirements set forth at § 512.220(a); and for all Technical participants. 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-calendar year (CY) period that begins on January 1 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 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.
- **Model performance period –** the five PYs [performance years] during which RO episodes must initiate and terminate.
- **Performance year (PY) –** 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 that date and end on December 31 of the same year.
- **Stop loss reconciliation amount –** the amount owed to RO participants that have fewer than 60 episodes during the baseline period 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 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 (OMB). Providers and suppliers are linked to a CBSA by the 5-digit ZIP code as reported on the claim form for where the services were provided as credentialed with CMS.

Since many RT providers and suppliers may not know what CBSA their services are provided in, to ensure understanding of which providers are randomly selected CMS published the list of ZIP codes that correlate to the randomly selected CBSAs. The full list of selected ZIP codes can be found on RO Model website.

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There are a few exclusions of those who may be part of the RO Model. Any physician practice groups, freestanding centers or hospital outpatient departments which furnish radiation oncology services in or paid under the systems listed below would be excluded even if in the randomly selected CBSAs. This is due to the potential overlap or interference in already established payment systems of reimbursement for radiation oncology services.

- State of Maryland
  - Excluded due to statewide payment model
- State of Vermont
  - Excluded due to All-Payer ACO (Affordable Care Organization)
- U.S. Territories
  - Due to low volume of radiation oncology services provided
- Ambulatory surgical centers (ASCs)
  - Due to low volume of radiation oncology services provided
- Critical access hospitals (CAHs)
  - Due to differences in how payments are made by CMS currently
- Prospective Payment System (PPS)-exempt cancer hospitals
  - Due to differences in how payments are made by CMS currently
- Hospital outpatient departments (HOPDs) actively participating in Pennsylvania Rural Health Model (PARHM) – **updated for 2022**
  - Due to payments under different model, if participant stops participation in PARHM and in an eligible CBSA, then participation in RO Model required.
- Community Health Access and Rural Transformation (CHART) – **updated for 2022**
  - 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

If the status or location of a provider or supplier changes during the time the model is in effect, this may exclude or require participation. For example, if a 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 also would be true if a center began in Maryland and moved to a randomly selected CBSA, the location would be required to participate as of the date of the location change. This applies to physicians or physician groups that move during the 5-year span of the RO Model or any HOPD or freestanding cancer center. It would also apply to any of the entities in which their status changed from PPS-exempt.

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

CMS previously finalized a low volume opt-out option for selected participants 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 selected CBSAs to participate, prior to the applicable performance year (PY), they may elect to opt-out of the PY.

CMS has removed any incentive for RO participants from changing their TIN or CCN as a means to become eligible for the low volume opt-out. An entity would not be eligible to opt-out if its legacy TIN or legacy CCN

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was used to bill Medicare for 20 or more episodes or RO episodes, as applicable, of RT services in two years prior to the corresponding performance year in a selected CBSA. CMS will include episodes and RO episodes associated with the RO participant's current CCN or TIN as well as any 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 31st 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 a there is an incomplete episode and the beneficiary no longer has traditional fee-for-service (FFS) Medicare before all of the RT services are provided in the episode, payment would be reconciled to what was provided professionally and technically using the no-pay claims. CMS would then pay for the services rendered as if they 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 sixteen (16) cancer types for services provided to a RO beneficiary during a 90-day episode of care were finalized. After consideration and stakeholder feedback CMS removed liver diagnosis from the cancer types included.

CMS indicated liver cancer and the radiation therapy services used to treat it are evolving. Various randomized trials do not include radiation therapy as a first-line therapy. Due to this and stakeholder feedback CMS removed liver diagnosis and now only include fifteen (15) cancer types.

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 incidence of cancer types; and
3. Have demonstrated pricing stability.

The following table provides the updated proposed ICD-10-CM codes as part of 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).

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TABLE 74: Included Cancer Types and Corresponding ICD-10 Codes	
Cancer Type	**ICD-10 Codes**
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.5x
Brain Metastases	C79.3x
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 Caner	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx
Uterine Cancer	C54.xx, C55.xx

Assignment of Cancer Types to an Episode

CMS did provide some language on how they will analyze and determine the episode's cancer type assignment according to an algorithm. The following is what CMS clarified as to their 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 or bone metastases or secondary malignancies (per the mapping of ICD–10 diagnosis code to cancer type described in Table 57 of Identified Cancer Types and Corresponding ICD–10 Codes), CMS 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 the cancer type with the highest claim line count among all other cancer types. CSM 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 the national base rate calculations.

CMS also addressed when there are not at least two claim lines for a diagnosis, like brain mets or bone mets as outlined in example 2 above, they would then assign the episode the cancer type with the highest line count among all other cancer types.

In reviewing this verbiage there are questions 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 is only possible on the CMS1500 claim form. Clarification is needed from CMS to determine if the CMS1500 claim by the physician will always determine the assignment since pointers cannot be used on the UB04 claim by the hospital.

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Included Radiation Therapy Services

CMS is not including evaluation and management (E/M) services within the RO Model. This is primarily due to the fact the 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, 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. This is due to stakeholder feedback which indicated because of the 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 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 by stating they do 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 brachytherapy is excluded does not speak to any lesser value it presents as a modality to treat patients. Published clinical evidence suggests it is highly valued and meets the criteria for inclusion; however, the concerns by stakeholders and the potential unintended consequences could have an impact and CMS acknowledged this. CMS will continue to monitor utilization, both as a single and multi-modality for RO participants compared to non-participants.

CMS sought comments on whether intraoperative radiotherapy (IORT) should be included in the RO Model. CMS received stakeholder feedback requesting it be added; however, due to the fact it 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 CMS does not believe it is appropriate for inclusion but sought comments on whether it should be considered. CMS did receive feedback and will consider for future rulemaking, but did not add for inclusion at this time.

The following is the list of HCPCS codes considered bundled into the RO Model. This updated list reflects the removal of the brachytherapy codes as finalized. The codes listed below will still be required for submission on a no-pay claim to CMS to support the services provided to the patient as part of the episode of care.

List of RO Model Bundled HCPCS		
HCPCS	**HCPCS Description**	**Category**
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placement	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services

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HCPCS	HCPCS Description	Category
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Telethx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Telethx isodose plan cplx	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77321	Special teletx port plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77331	Special radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77332	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery
77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery
77522	Proton trmt simple w/comp	Radiation Treatment Delivery
77523	Proton trmt intermediate	Radiation Treatment Delivery
77525	Proton treatment complex	Radiation Treatment Delivery
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)

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HCPCS	HCPCS Description	Category
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)

Pricing Methodology

The pricing methodology includes eight primary steps to be applied to each cancer type to determine the overall reimbursement.

Step one, national base rates will be created by CMS for the PC and TC components of the included cancer types. The 15 cancer types which would result in 30 different base rates (15 for the professional and 15 for the technical). The rates would reflect a national historical average cost for each cancer type and episode of care as based on claims data from a 3-year period.

Step two, trend factor accounts for current trends in payment for RT services and the volume of these same services outside the RO Model under HOPPS and MPFS. It will also ensure the 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. These factors will be made available by CMS on RO Model website prior to the PY after CMS issues the annual HOPPS and MPFS final rules for the upcoming year.

Step three, 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 participants paid under 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 (PE) and malpractice (MP) RVUs. Table 59 from the CY 2022 proposed rule reflects an example of the RVU Shares of each PC and TC for the RO Model utilizing the final year of the 3-year baseline to determine the implied RVU shares.

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TABLE 59: RVU SHARES (CY 2022 Proposed Rule Data)					
RVU Shares					
Professional Component			Technical Component		
Work	PE	MP	Work	PE	MP
0.65	0.31	0.04	0	0.99	0.01

Step four, the national base rate will be adjusted to account for each Participant's historical experience and case mix history 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 2017-2019. These values will be calculated by CMS and provided to each participant at least 30 days prior to the next PY. The equations would look something like this,

- Case mix adjustment = (predicted payment-expected payment)/expected payment
- Historical experience adjustment = (Winsorized payments-predicted payments)/expected payments

Step five, 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 and other previous adjustments have been applied. CMS is adjusting the previously finalized discount factors. For CY 2022 CMS set a discount factor of 3.50 percent for PC and 4.50 percent for TC, a 0.25 percent reduction for each respectively.

Step six, 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 1 percent beginning performance year 3 (PY3) for TC payments related to the patient experience withhold. There are essentially two categories of withhold by CMS as a means to potentially avert any incomplete episodes or duplicate billing for bundled services which would result in incorrect payment and those related to the quality and patient experience.

Steps seven and eight, 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 has finalized the National Base Rates and HCPCS codes for reporting the professional and technical services as listed in Table 75 of the final rule, these are the same as proposed. CMS will no longer reference the specific CYs from the definition baseline period, instead the 3-year span used to determine the weighting and rates will be based on 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 they will weigh the more recent episodes more heavily in the baseline period than those earlier in the baseline period. For example, 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 model, all of Maryland and Vermont, CAHs, etc. as well as those participating in PARHM, 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 3-year calculation for what is included.

The following table lists the proposed rates per PC and TC as well as the HCPCS codes used to identify the cancer type and billed when starting and stopping the episode of care.

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Table 75 -National Base Rates			
RO Model-Specific 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

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CMS provided two examples of the 8-step pricing methodology in the CY 2022 HOPPS proposed rule, an example lung case reflecting the PC and TC separately is provided. Tables 60 and 61 reflect these examples as provided by CMS and are provided here again in this summary for reference.

TABLE 60: Example: Participant-Specific Professional Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.) (CY 2022 Proposed Rule Data)

	Professional Component	
	Amount	**Formula**
National Base Rate (a)	$2,231.40	
Trend Factor (b)	1.04	
Subtotal (c)	$2,320.66	c = a * b
SPLIT for SOE/EOE payments (d)	$1,160.33	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$1,183.53	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.14	e.g. (116-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.15	j = g + (h * i) + 1
Subtotal (k)	$1,356.33	k = j * f
Discount Factor (l)	0.9650	
Subtotal (m)	$1,308.86	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Quality Performance) (o)	0.98	
Total Withhold (p)	0.97	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$1,269.59	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$253.92	r = q * 0.20
SOE Participant Payment	$1,015.67	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$995.36	t = s * 0.98
Episode Payment 1: SOE (u)*	**$995.36**	**u = t**
Episode Payment 2: EOE (v)*	**$995.36**	**v = t**
Total Episode Payment to RO Participant (w)	**$2,498.56**	**w = u+v+2r**

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TABLE 61: Example: Participant-Specific Technical Episode Payment for Lung Cancer in PY1 (All numbers are illustrative only.) (CY 2022 Proposed Rule Data)

	Technical Component	
	Amount	**Formula**
National Base Rate (a)	$12,142.39	
Trend Factor (b)	1.04	
Subtotal (c)	$12,628.09	c = a * b
SPLIT for SOE/EOE payments (d)	$6,314.04	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$6,440.32	f = d * e
Case Mix Adjustment (g)	0.02	e.g. (102-100) / 100
Historical Experience Adjuster (h)	0.11	e.g. (113-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.12	j = g + (h * i) + 1
Subtotal (k)	$7,206.72	k = j * f
Discount Factor (l)	0.9550	
Subtotal (m)	$6,882.42	m = l * k
Withhold #1 (Incorrect Payment) (n)	0.99	
Withhold #2 (Patient Experience) - not applied until PY3 (o)		
Total Withhold (p)	0.99	p = 1-((1-n)+(1-o))
Half of Total Episode Payment to RO Participant without sequestration (q)	$6,813.60	q = p * m
Beneficiary Coinsurance for SOE payment Determined (r)	$1,362.72	r = q * 0.20
SOE Participant Payment	$5,450.88	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$5,341.86	t = s * 0.98
Episode Payment 1: SOE (u)*	**$5,341.86**	**u = t**
Episode Payment 2: EOE (v)*	**$5,341.86**	**v = t**
Total Episode Payment to RO Participant (w)	**$13,409.16**	**w = u+v+2r**

Quality Measure Reporting for Professional and Dual Participants

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

- Oncology: Medical and Radiation - Plan of Care for Pain -*NQF41 #0383; CMS Quality ID #144*
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan -*NQF #0418; CMS Quality ID #134*
- Advance Care Plan -*NQF #0326; CMS Quality ID #047*

The fourth measure would also be required to be reported, but this 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 they will update the specifications of the following measure should new

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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.

- Treatment Summary Communication – Radiation Oncology

CMS will also be using the CAHPS® Cancer Care Survey to evaluate RO beneficiary experience as part of the RO Model. Due to the timeline changes in the RO Model, 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.

Professional and Dual participants must collect certain clinical information not available in the 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 (CDEs) 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 above for each). Technical participants that are freestanding radiation therapy centers (as identified by a TIN) that only provide the technical component (TC) 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 https://qpp.cms.gov/.

Extreme and Uncontrollable Circumstances Policy

There may be circumstances outside the control of RO 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 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 EUC 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.

Geographic region(s) which 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 done to determine eligible participants.

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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 PC and/or TC of the included cancer type.

CMS has many additional resources, webinars, and tools available on the RO Model website. It is recommended to review these resources and register for the educational webinars.

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