

# **Radiation Oncology Model Frequently Asked Questions (FAQs)**

**December 1, 2020**

## ***Disclaimer***

*The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law.*

<b>Abbreviation</b>	<b>Term</b>
CBSA	Core Based Statistical Area
CCN	CMS Certification Number
CWF	Common Working File
EOE	End of Episode
FFS	Fee for Service
HCPCS	Healthcare Common Procedure Coding System
HOPD	Hospital Outpatient Department
MAC	Medicare Administrative Contractor
MLN	Medicare Learning Network
PFS	Medicare Physician Fee Schedule
OPPS	Outpatient Prospective Payment System
PAMPA	Patient Access and Medicare Protection Act
PC	Professional Component
PGP	Physician Group Practice
RO	Radiation Oncology
RT	Radiation Therapy or Radiotherapy
SOE	Start of Episode
TIN	Tax Identification Number

The RO Model will regularly update these FAQs as new questions come in through the Helpdesk and webinars. Questions that have been added to this set of FAQs are noted with [NEW] and questions that have been revised since the last version are noted with [REVISED].

## **CMMI Innovation Center**

### **1. What statute authorizes the Centers for Medicare & Medicaid Services (CMS) to develop and test the Radiation Oncology (RO) Model?**

Section 1115A of the Social Security Act (the Act) authorizes the Center for Medicare and Medicaid Innovation (Innovation Center) to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished for beneficiaries of such programs. The Innovation Center designed the Radiation Oncology Model (RO Model or the Model) as a patient-centric model for Medicare fee-for-service (FFS) beneficiaries receiving radiation therapy or radiotherapy (RT) services for cancer care.

## **RO Model Overview**

### **2. What is the goal of the RO Model?**

The RO Model will test whether prospective, episode-based payments to physician group practices (PGPs) (including freestanding radiation therapy centers) and hospital outpatient departments (HOPDs), for radiotherapy (RT) episodes of care will reduce Medicare program expenditures and preserve or enhance quality of care for Medicare beneficiaries.

### **3. How will the RO Model support the goals of reducing Medicare expenditures?**

The RO Model will advance CMS' goal of increasingly paying for value and outcomes, rather than for volume of services alone. By promoting the alignment of financial and other incentives for radiotherapy (RT) providers and RT suppliers caring for beneficiaries receiving RT services for cancer, the Model will offer RO participants the opportunity to examine and better understand their own care processes and patterns, which we believe may lead to significant opportunities to redesign care and improve the quality of care furnished to beneficiaries.

### **4. How will the RO Model help beneficiaries?**

The RO Model incentivizes the delivery of higher-value radiotherapy (RT) care, allowing physicians to select the type and amount of radiation treatment that offer patients the best value in terms of cost and quality. By eliminating financial incentives to provide extended fractionation treatment schedules in the current payment systems, participants in the RO Model have the flexibility to provide fewer fractions of radiation when clinically appropriate. Beneficiaries will benefit from receiving high quality treatment in fewer encounters, improved quality of life during RT treatment, and the shorter courses of RT will be equally effective and potentially less costly for the Medicare program which can lead to reductions in beneficiary cost-sharing, improving the patient experience overall. Finally, the RO Model aims to support clinical practice transformation, reduce administrative burden through a simplified and predictable payment system that moves Medicare toward site-neutrality, and improve beneficiary experience by rewarding high-quality patient-centered care.

## **5. What are the defining elements of the RO Model?**

The RO Model's design offers site-neutral prospective, modality agnostic, episode-based payments to physician group practices (PGPs), hospital outpatient departments (HOPDs), and freestanding radiation therapy centers for 16 cancer types. These episode-based payments will replace fee-for-service (FFS) payments for certain radiotherapy (RT) services included in a 90-day episode. The RO Model will be evaluated to determine if a prospective episode-based payment model can improve the quality of care cancer patients receive and improve patient experience by rewarding high quality care that results in better outcomes. Another defining element of the RO Model is that eligible participants will be required to participate.

## **6. How does the RO Model define an episode?**

The RO Model distinguishes between an "RO episode" and an "episode." An "RO episode" is defined as the 90-day period that begins on the date of service that a Professional participant or a Dual participant furnishes an initial treatment planning service to an RO beneficiary in a freestanding radiation therapy center or an HOPD, provided that a Technical participant or the same Dual participant furnishes a technical component RT service to the RO beneficiary within 28 days of such RT treatment planning service. An "episode" is defined as the 90-day period of RT services that begins on the date of service that an RT provider or RT supplier that is not an RO participant furnishes an initial treatment planning service to a beneficiary, provided that an RT provider or RT supplier furnishes a technical component RT service to the beneficiary within 28 days of such initial treatment planning service. Additional criteria for constructing episodes to be included in determining the national base rates are set forth in § 512.250. "Episodes" generally refer to the data used to create the case mix adjustment, and does not occur within the performance year (with the exception of PY3, which uses episodes from 2018 – 2020 to create the case mix adjustment).

## **7. Who participates in the RO Model?**

The RO Model requires participation from RT providers and RT suppliers that furnish RT services within randomly selected Core-Based Statistical Areas (CBSAs). The CBSAs selected for the RO Model contain approximately 30 percent of all eligible Medicare fee-for-service (FFS) radiotherapy episodes nationally. An RO participant can be a physician group practice (PGP), a freestanding radiation therapy center, or a hospital outpatient department (HOPD) that furnishes RT services in a CBSA that is randomly selected for participation. A ZIP-code look-up tool, which provides all five-digit ZIP Codes linked to these selected CBSAs, is available on the [RO Model website](#). All RO participants are designated as either a Professional participant (one that furnishes only the professional component of RT services), a Technical participant (one that furnishes only the technical component of RT services), or a Dual participant (one that furnishes both the professional and technical components of RT services).

## **8. What is the difference between a Professional participant, Technical participant, and Dual participant?**

A Professional participant is a Medicare-enrolled PGP, identified by a single Taxpayer Identification Number (TIN) that furnishes only the Professional component (PC) of RT services at either a freestanding radiation therapy center or a hospital outpatient department (HOPD). A Technical participant is a HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the Technical component (TC) of RT services. A Dual participant furnishes both the PC and TC of an RO episode for RT services through a freestanding radiation therapy center, identified by a single TIN. This distinction between the PC and the TC of RT services reflects the fact that these services are sometimes furnished by separate RT providers and RT suppliers and paid for through

different payment systems (namely, the Medicare Physician Fee Schedule and Outpatient Prospective Payment System).

#### **9. Why is participation required under the RO Model?**

Through discussions with RT experts, evaluation experts, and actuaries, CMS determined that required participation is the best approach to test the proposed episodic payment effectively by ensuring sufficient proportional participation of both HOPDs and freestanding radiation therapy centers, which is necessary to obtain a diverse, representative sample of RT providers and RT suppliers and to help support a statistically robust test of the prospective episode payments made under the RO Model. Testing the RO Model in this manner also allows us to learn more about patterns of utilization of health care services and how to incentivize the improvement of quality for RT services. For these reasons, we believe that required participation is the best way to detect and observe the impact of the prospective episode-based payments made under the RO Model.

#### **10. In which facilities will the RO Model be implemented?**

The RO Model will be implemented in physician group practices (PGPs), hospital outpatient departments (HOPDs), and freestanding radiation therapy centers that furnish RT services in Core-Based Statistical Areas (CBSAs) randomly selected for participation. A ZIP Code look-up tool, which provides all five-digit ZIP Codes linked to the selected CBSAs, is available on the [RO Model website](#). The RO Model will be implemented in PGPs, HOPDs, and freestanding radiation therapy centers furnishing RT services in one or more of those ZIP Codes.

#### **11. Why does the RO Model include both freestanding (non-facility) and hospital outpatient department radiation therapy centers?**

CMS learned through its engagement with RT stakeholders that there is strong support for site-neutral payment system for RT. Because RT services do not differ based on the site of service, the RO Model creates an opportunity to test a new site neutral payment structure that is both logically sound and supported by the industry. Site-neutral payments are currently a CMS-wide focus.

#### **12. How does the RO Model differ from the Oncology Care Model (OCM)?**

The OCM Model is a total cost of care model, which includes all the care a beneficiary receives, and includes a broader set of oncology services than the RO Model, such as chemotherapy. The RO Model is a prospective, episode-based payment model, which means that RT providers are paid a predetermined rate per cancer type for a 90-day episode of treatment, for included RT services. The RO Model complements the OCM evidence base in several ways, including its specific focus on radiation oncology, its innovative payment structure and alignment with private sector models, and its potential to greatly increase the information the Innovation Center has regarding RT pricing, care delivery, and overall treatment decisions. By focusing on prospective payment for RT, the RO Model will provide further insight into the effects of alternative payment on oncology care outcomes and experience for patients beyond what is currently underway in other models, such as the OCM. The additional insights into RT services are important as the incidence of cancer is expected to increase, along with the use of RT as a core method of treatment.

#### **13. [REVISED] When does the RO Model start and end?**

The RO Model's first performance year (PY) was originally finalized to take place from January 1, 2021 through December 31, 2021. CMS has received feedback from a number of stakeholders about the challenges of preparing to implement the RO Model by January 1, 2021. Based on this feedback, CMS has released an interim final rule with comment to delay the RO Model start date to July 1, 2021.

There will be 4.5 PYs, with the final PY ending on December 31, 2025. No new RO episodes may begin after October 3, 2025 to ensure all RO episodes are completed by December 31, 2025 (i.e. RO participants may not submit claims for a bundled payment for a new RO episode after October 3, 2025, which is fewer than 90 days before the end of the RO Model). The lag in data collection will mean that data collection, episode payments, and payment reconciliation will continue into calendar year 2026.

#### **14. [NEW] What impact will the delay have on the RO Model?**

- The first performance year (PY) will be from July 1, 2021-December 31, 2021.
- The Model performance period will be 4.5 years.
- We expect the RO Model will qualify as an Advanced Alternative Payment Model (APM) and a Merit-based Incentive Payment System (MIPS) APM under the CMS Quality Payment Program (QPP) beginning in PY2.
- Certified Electronic Health Record Technology (CEHRT) will be a requirement starting in PY2.
- The individual practitioner list (IPL) will still be required in PY1, but it will only be used for QPP in PY1 to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants.
- RO participants must, beginning in PY2, collect quality measures data from January 1, 2022, through December 31, 2022 and submit in March 2023. As quality measures are not being collected until PY2 there will be no quality withhold for PY1.
- A CMS-approved contractor will administer the CAHPS® Cancer Care Survey for Radiation Therapy beginning in October 2021 instead of April 2021.
- The collection period for clinical data elements (CDEs) will begin on January 1, 2022. The first submission of the clinical data elements for January 1, 2022 through June 30, 2022 will be due in July 2022.

Impact of the delay is detailed in the interim final rule with comment period (CMS-1736-IFC).

#### **15. [REVISED] What are the major requirement deadlines throughout a performance year (PY)?**

There are several deadlines throughout the PY that RO participants should be aware of, based on the following timelines:

- *30 days prior to the start of a PY:* 1) CMS makes case mix and historical experience rates available to RO participants; 2) RT suppliers and RT providers who are eligible for the RO Model but meet the low-volume opt-out option requirements must notify CMS of their decision to opt-out; 3) RO Professional and Dual participants must attest that they are using Certified Electronic Health Record Technology (CEHRT) for PY2-PY5
- Within 30 days of the receipt of the individual practitioner list (IPL), RO participants must review and certify the IPL
- January 1: PYs 2-5 begin
- January: Clinical Data Elements (CDE) submission, covering the previous July – December (only applies in PY2-PY5)
- March: Beginning in March 2022, RO participants must submit Quality Measure data collected during PY1
- July: CDE submission, covering January – June (PYs 2-5)

- December 31: Each PY ends
- August: Payment reconciliation (based on previous PY)

## RO Model Operational Support

### **16. [REVISED] What is the process for RO participants to establish their Model ID?**

RO participants must first call the RO Model Help Desk to receive their Model ID number. The Help Desk can be reached at 1-844-711-2664, option 5. Participants must provide their Taxpayer Identification Number (TIN) if they are a physician group practice or freestanding radiation therapy center or CMS Certification Number (CCN) if they are a hospital outpatient department to be able to retrieve their Model ID from the Help Desk. Please note that participants may provide their CCN by email, but participants must not communicate TINs via email as this is considered Personally Identifiable Information (PII).

Participants will also need to supply the first name, last name, and email address of a primary contact. For security purposes, we need to preload this primary contact information for every RO participant into each RO Model-specific data portal. To register for any of these portals, RO participants will need to use this same information along with their Model ID and CCN or TIN.

The Model ID is critical; it is what will give RO participants the ability to log into the Radiation Oncology Administrative Portal (ROAP), the RO Model Secure Data Portal, and the Radiation Oncology Connect site. If an RO participant does not ascertain their Model ID, by default they will not be able to meet certain RO Model requirements or submit quality measure and clinical data elements, which will then not allow participants the opportunity to earn back a portion of the quality and patient experience withholds.

At this time, Points of Contact (POC) can only be associated with one Model ID. We apologize for any inconvenience. We are working with programmers to remedy this situation as quickly as possible. In the meantime, you can register a distinct Primary contact and Legal contact for each Model ID. Once that person logs into ROAP, they can add additional people to the contact list. If you wish to remain as the Primary contact for multiple Model IDs, we anticipate this issue will be fixed by mid-January.

### **17. What is the Radiation Oncology Administrative Portal (ROAP)?**

The ROAP is an online platform that CMS uses to track participant information through the participant profile page. For RO participants, the ROAP provides access to the following functions:

- Access and review organizational data
- Access participant specific data, including Historical Experience and Case Mix adjustments, and Performance Reports
- Update participant information and contacts
- Download and submit Data Request and Attestation (DRA) forms
- Attest to the use of the Certified Electronic Health Record Technology (CEHRT), revise the Individual Practitioner Lists, and attest to participating with a Patient Safety Organization
- Notify CMS of the RO participant's intention to opt out of the upcoming Performance Year, if they so qualify.

## **18. How do RO participants access the Radiation Oncology Administrative Portal (ROAP)?**

To access the ROAP, navigate to the [login page](#), and select “Register here.” To Register, you will need to enter your Model ID, Taxpayer Identification Number (TIN) or CMS Certification Number (CCN), and the first name, last name, and email address of the primary contact in the appropriate fields.

Reminder: Hospital outpatient departments (HOPDs) should provide their CCN and physician group practices (PGPs) or freestanding radiation therapy centers should provide the TIN that the practice bills under.

## **19. What do I do if I need help with the Radiation Oncology Administrative Portal (ROAP)?**

ROAP User Manual: For further instructions on logging in to ROAP, please find the ROAP User Manual in the “Radiation Oncology Administrative Portal (ROAP)” section on the Radiation Oncology (RO) Model web page. The ROAP User Manual can be found here: <https://innovation.cms.gov/media/document/ro-model-admin-portal-user-manual>

Help Desk Support: If you have issues logging onto ROAP, please contact CMMIForceSupport@cms.hhs.gov or call 1-888-734-6433, option 5.

Office Hours: RO participants can call into standing Office Hours that have been set up to help troubleshoot ROAP login issues. Email notifications with further information about the schedule and call-in information for the Office Hours will be sent to RO participants.

## **20. [REVISED] What is the difference between primary, secondary, and legal contacts?**

*Primary Contact:* A primary contact is necessary to register for the Radiation Oncology Administrative Portal (ROAP) the first time. For security purposes, we need to preload the first name, last name, and email address of the primary contact for every RO participant into ROAP. Please call the Helpdesk with this information if you have not already done so. To register for ROAP, you will need to use this same information along with your Model ID and Taxpayer Identification Number (TIN) or CMS Certification Number (CCN).

*Once you access ROAP, a primary contact can:*

- Add, delete, or edit contact information including contact type and phone number for other primary contacts, and for legal and secondary contacts (Please note you are not able to edit the contact’s first name, last name, or email after this contact had been registered in ROAP. Please contact the Helpdesk if you need to edit this information);
- Edit profile information (Not able to edit Legal Name, Model ID, and CCN or TIN);
- Add or drop providers/practitioners on the Individual Practitioner List (IPL);
- Add a Sanction;
- Answer the optional Administrative Questions; and
- Add Organization Changes.

*Legal Contact:* Every Model ID must have at least one legal contact in ROAP. A legal contact can:

- Add, delete, or edit contact information including contact type and phone number for other legal contacts, and for primary and secondary contacts (please note you are not able to edit the contact’s first name, last name, or email after this contact had been registered in ROAP. Please contact the Helpdesk if you need to edit this information);

- Edit profile information (Not able to edit Model ID, CCN or TIN);
- Download the Data Request and Attestation (DRA) template and upload the completed DRA form;
- Attest to the use of Certified Electronic Health Record Technology (CEHRT) during the specified period;
- Add or drop practitioners on the Individual Practitioner List (IPL);
- Attest to the accuracy of the IPL during the specified period;
- Attest to active participation in a Patient Safety Organization (PSO) during the specified period;
- Download a Corrective Action Plan (CAP) from CMS and upload a CAP response;
- Add a Sanction;
- Answer the optional Administrative Questions;
- Choose to opt out of the RO Model if the participant is eligible for the low volume opt-out; and
- Add Organization Changes.

*A Secondary Contact can:*

- View information in ROAP for their Model ID, but they cannot edit information.

*All contacts can:*

- Download performance, compliance, and reconciliation reports; and
- Download the Case Mix and Historical Experience Adjustments.

*Please Note:* To register for ROAP, every Model ID must have a Primary contact. Within ROAP, every Model ID must also have a Legal contact to complete certain tasks, like upload the DRA, make attestations, select the low volume opt-out if eligible, etc. The Primary contact and Legal contact may not use the same email address.

If you are an RO participant who only has one point of contact for your Model ID, you will be added as a Primary contact when you first register for ROAP. If there is no one else in your practice who can serve as the Legal contact, you can request to switch yourself from a Primary contact to a Legal contact. To make this request, please contact [CMMIForceSupport@cms.hhs.gov](mailto:CMMIForceSupport@cms.hhs.gov) or call 1-888-734-6433, option 5.

### **21. Why is my Data Request and Attestation (DRA) greyed-out?**

The DRA requires a legal point of contact to download the DRA template and upload the completed form. Anyone other than the legal point of contact will see the upload function greyed-out.

### **22. What is the RO Model Secure Data Portal?**

RO participants who request beneficiary line-level claims data, episode-level data, and participant-level data via the ROAP will receive the requested data via the RO Model Secure Data Portal. To request this data, RO participants will use a Participant Data Request and Attestation (DRA) form, if appropriate for that RO participant's situation, which will be available on the Radiation Oncology Administrative Portal (ROAP). Throughout the Model performance period, RO participants may request to continue to receive this data until the initial reconciliation and true-up reconciliation have been completed if they continue to use such data for care coordination and quality improvement purposes. At the conclusion of this process, the RO participant would be required to maintain or destroy all data in its possession in

accordance with the DRA and applicable law. The RO Model Secure Data Portal will be accessible on the RO Model website shortly.

**23. Do the points of contact for the Radiation Oncology Administrative Portal (ROAP) and the RO Model Secure Data Portal need to be the same?**

No, we do not use point of contacts in the RO Model Secure Data Portal. There are two roles that you request in the RO Model Secure Data Portal: RO Model Participant and Data Requestor. The RO Model Participant role will be able to download and upload Clinical and Quality Data. The Data Requestor Role should be the person listed on the Data Request and Attestation (DRA) form as the data custodian and should be a contact in ROAP. The Data Requestor role can download claims data and download and upload Clinical and Quality Data. We will continue to share more information on the RO Model Secure Data Portal, and we will send out an email blast when the Secure Portal is ready for use.

**24. What is the Radiation Oncology Connect Site?**

The RO Model Connect Site is a collaborative resource site for the RO Model. Participants and the RO Model team use this site for sharing documents, participating in online discussions, and receiving updates about RO Model activities, among other features. The RO Model Connect Site Library contains technical and operational resource documents important for program implementation, as well as audio-visual recordings and transcripts of RO Model learning events. The RO Model Connect Site will be available in December.

**25. What is the CMS Enterprise Data Portal?**

The CMS Enterprise Data Portal is the entry point for several CMS systems. Please refer to [this link](#) for instructions on how to register in the CMS Enterprise Portal (EIDM).

## **RT Provider and RT Supplier Eligibility in the RO Model**

**26. In which geographic areas will CMS operate the RO Model?**

The RO Model will operate in defined, randomly selected, stratified Core-Based Statistical Areas (CBSAs). A CBSA is a statistical geographic area with a population of at least 10,000, which consists of a county or counties anchored by at least one core (i.e., urbanized area or urban cluster), plus adjacent counties having a high degree of social and economic integration with the core (as measured through commuting ties with the counties containing the core). CBSAs are large enough to capture relevant markets and referral patterns in a geographic area. CBSAs capture the diversity of RT providers and RT suppliers that may be affected by the RO Model without including rural RT providers and RT suppliers as designated by CMS and Health Resources and Services Administration (HRSA). There are very few RT providers and RT suppliers in these areas such that, if included, the areas would likely not have enough RO beneficiaries, and thus not generate enough RO episodes, for inclusion in the statistical analysis.

**27. How do I know if I am required to participate in the RO Model?**

A ZIP Code look up tool on the [RO Model website](#) provides all five-digit ZIP Codes linked to the selected Core-Based Statistical Areas (CBSAs), in accordance with the selection policy described in section III.C.3.d of the final rule. RT providers and RT suppliers that furnish RT services in any of those ZIP Codes will be required to participate in the RO Model. Hospital outpatient departments (HOPDs) that are part of a hospital or critical access hospital (CAH) participating in or eligible to participate in the Pennsylvania Rural Health Model (PARHM) are excluded from the RO Model. Please reference the PARHM website at <https://innovation.cms.gov/innovation-models/pa-rural-health-model> for a list of hospitals and CAHs

that are eligible to participate in PARHM, which may be used to identify the specific HOPDs that are excluded from participation in the RO Model. In addition, any RT provider or RT supplier that furnishes fewer than 20 episodes or RO episodes across the CBSAs selected for participation in the most recent year with data available will have the ability to opt out of the RO Model for the upcoming performance year (PY) on the Radiation Oncology Administrative Portal (ROAP). Note that the RT providers and RT suppliers that qualify for the opt-out option are still RO participants and must still register and opt-out of the RO Model via ROAP annually. Furthermore, it is possible for an RT provider or RT supplier to be eligible one year and then ineligible the following year based on the number of episodes or RO episodes provided in the most recent calendar year with claims data. In this case, the RO participant must log on to ROAP and attest to the intention of opting out of the RO Model prior to the start of the applicable PY if they qualify to do so.

**28. What if my ZIP Code straddles more than one Core-Based Statistical Areas (CBSA)?**

Not all five-digit ZIP Codes fall entirely within OMB-delineated CBSA boundaries, resulting in some five-digit ZIP Codes assigned to two different CBSAs. Approximately 15 percent of five-digit ZIP Codes have portions of their addresses located in more than one CBSA. Rather than increase provider burden by requiring submission of more detailed geographic data by RT providers and RT suppliers, the RO Model assigns the entire five-digit ZIP Code to the CBSA where the ZIP Code has the greatest portion of total addresses (business, residence, and other addresses) such that each five-digit ZIP Code is clearly linked to a unique CBSA or non-CBSA geography. In cases where the portion of total addresses within the five-digit ZIP Code is equal across CBSAs and cannot be used to make the link, CMS gives precedence to the five-digit ZIP Code in which the greater portion of business addresses are located.

**29. What anchors an episode to a ZIP Code to determine if the episode is included in (i.e. paid for under) the RO Model?**

Both the Professional component (PC) and the Technical component (TC) of the RT services must be furnished within an included ZIP Code for the RO episode to be counted in the Model. In other words, the address of the service location where the PC and TC are furnished must be in an included ZIP Code as opposed to the billing address.

**30. What happens if my practice has multiple locations, some in an included ZIP Code and some in an excluded ZIP Code?**

If your practice has multiple locations, only those with site of service addresses with an included ZIP Code will be RO participants. Having one included ZIP Code does not automatically mean all locations are in the Model. Billing address does not determine participation.

In other words, if your organization furnishes RT services in various locations, only those furnishing services within participating ZIP Codes are RO participants. Other locations would not be responsible for following RO Model requirements.

**31. Why is my ZIP Code included for participation in the RO Model when my practice furnishes RT services in a rural community?**

The use of Core-Based Statistical Areas (CBSAs) and their corresponding ZIP Codes is intended to capture the diversity of RT providers and RT suppliers that may be affected by the RO Model. The RO Model was not designed to exclude rural RT providers and RT suppliers. Generally, CBSAs and their corresponding ZIP Codes do not include extreme rural regions, but they do contain rural RT providers and RT suppliers as designated by CMS and Health Resources and Services Administration (HRSA). In cases where RO participants are furnishing RT services in rural communities, the historical experience adjustment will

account for those RO participants' historical care patterns and their relative cost, so long as they furnished at least 60 episodes during 2016-2018 baseline period. In addition, if a RO participant has furnished fewer than 20 episodes in 2019 among the CBSAs and their corresponding ZIP Codes selected for participation in the RO Model, then they are eligible for the low volume opt-out for performance year 1.

**32. If there are multiple facilities under one Tax Identification Number (TIN) and only one facility is located in an included ZIP Code, will the other facilities also be included in the RO Model due to a common TIN?**

Only the facility that furnishes RT services in the included ZIP Code will be required to participate in the RO Model. Other locations will not be responsible for following RO Model requirements.

**33. Are any RT providers or RT suppliers who are ineligible to participate in the RO Model?**

Only RT providers and RT suppliers in the randomly selected Core-Based Statistical Areas (CBSAs) are eligible to participate in the RO Model. In addition to those entities that are not located in selected CBSAs, any physician group practice (PGP), freestanding radiation therapy center, or hospital outpatient department (HOPD) that meets the following criteria will also be excluded from the RO Model:

- Furnishes RT only in Maryland
- Furnishes RT only in Vermont
- Furnishes RT only in U.S. Territories
- Is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital (PCH)
- Participates in, or is identified as eligible to participate in, the Pennsylvania Rural Health Model

**34. [REVISED] If an RO participant furnishes radiotherapy (RT) in a randomly selected Core-Based Statistical Area (CBSA) but delivers a low volume of RT episodes, can it opt out of the RO Model?**

Any physician group practice (PGP), freestanding radiation therapy center, or hospital outpatient departments (HOPD) that is otherwise an eligible RO participant and furnishes fewer than 20 episodes or RO episodes based on available claims data within one or more CBSAs selected for participation in the most recent calendar year with available claims data, may elect to opt out of the RO Model under the model's "Low Volume Opt-Out" policy so long they attest to the intention of opting out of the Model prior to the start of the applicable performance year (PY). Prior to the start of each performance year, CMS will identify which RO participants are eligible to opt out of the RO Model (including the RO Model payments and participation requirements) based on the most recently available claims data. For PY1 (July 1, 2021 through December 31, 2021), CMS will use 2019 episodes; for PY2 (January 1, 2022 through December 31, 2022), CMS will use 2020 episodes, and so on. We will notify RO participants at least 30 days prior to the upcoming PY if they are eligible to opt out. This process will be repeated prior to each year of the RO Model. This could result in some RO participants being eligible for the opt-out option in some years and not others, that is, an RO participant could be able to opt out in one year and then be required to participate in the subsequent year. For example, an RO participant that has 20 or more episodes in 2020 and therefore not eligible for the low volume opt-out in PY2, may have fewer than 20 RO episodes in 2021 and therefore eligible for the low-volume opt-out in PY3.

**35. [REVISED] If a new entity did not furnish radiotherapy (RT) in a randomly selected Core-based Statistical Area (CBSA) in the period used to assess opt-out eligibility, can the entity opt out of the RO Model?**

Any physician group practice (PGP), freestanding radiation therapy center, or hospital outpatient departments (HOPD) that is otherwise an eligible RO participant and furnishes fewer than 20 episodes based on available claims data within one or more CBSAs selected for participation in the most recent calendar year with available claims data may elect to opt out of the RO Model via the model's "Low Volume Opt-Out" policy so long as they attest to the intention of opting out of the Model prior to the start of the applicable performance year (PY) (that is on or before June 30, 2021 for PY1 and on or before December 31 of the prior PY in which the opt-out would occur for PY2-PY5). Prior to the start of each RO Model PY, CMS will identify which RO participants are eligible to opt out of the RO Model (including the RO Model payments and participation requirements) based on the most recently available claims data. For PY1 (July 1, 2021 through December 31, 2021) CMS will use 2019-episode data; for PY2 (January 1, 2022 through December 31, 2022), CMS will use 2020 data, and so on. We will notify RO participants at least 30 days prior to the upcoming PY if they are eligible to opt out. This process will be repeated prior to each year of the RO Model. This could result in some RO participants being eligible for the opt-out option in some years and not others, that is, a RO participant could be able to opt out in one year and then be required to participate in the subsequent year. Examples of a change in business or billing arrangements that must be reported to CMS include, but are not limited to, changes in business or billing arrangements via:

- Merger
- Acquisition
- Addition of a new physician identified by a National Provider Identifiers (NPI) to a physician group practice (PGP)
- Addition of a new hospital outpatient department (HOPD) identified by a CMS Certification Number (CCN)
- Addition of a new freestanding radiation therapy center identified by a Taxpayer Identification Number (TIN)
- Any other new clinical or business relationship.

**36. Do RO participants need to notify CMS of changes in their business or billing arrangements during the Model performance period?**

RO participants must notify CMS of changes in business or billing arrangements at least 90 days before the effective date of the change. Examples of a change in business or billing arrangements that must be reported to CMS include, but are not limited to, changes in business or billing arrangements via:

- Merger
- Acquisition
- Addition of a new physician identified by a National Provider Identifiers (NPI) to a physician group practice (PGP)
- Addition of a new hospital outpatient department (HOPD) identified by a CMS Certification Number
- Addition of a new freestanding radiation therapy center identified by a Taxpayer Identification Number (TIN)

- Any other new clinical or business relationship

Participation requirements apply throughout the Model performance period, so if the new TIN or CCN begins to furnish RT services within a selected Core-Based Statistical Area (CBSA) as identified by ZIP Code between the start date and end of the Model, then, absent qualifying for the low-volume opt-out, it must participate in the RO Model and keep CMS apprised of all relevant changes.

**37. [REVISED] What happens if a new physician group practice (PGP), hospital outpatient department (HOPD), or freestanding radiation therapy center is established and furnishes services in a ZIP Code included in a selected Core-Based Statistical Area (CBSA)?**

If the new PGP, HOPD or freestanding radiation therapy center meets eligibility requirements under the RO Model, then the entity will be an RO participant. If there is not sufficient historical data for the entity, that is 60 episodes during the 2016-2018 baseline period, the entity will not receive an historical experience adjustment. The entity will also not have a case mix adjustment for the first year of participation. The RO participant may have a case mix adjustment in successive performance years (PY) if there is sufficient data in the applicable rolling 3-year period.

If your entity begins furnishing RT services during the Model performance period, reach out to the Help Desk to acquire the Model ID for your entity. You may need to provide the Help Desk with further information to procure the Model ID. New entities that furnish RT services in a participating ZIP Code are required to participate in the Model unless they qualify for the low volume opt-out for a given PY and attest to the intention of opting out of the Model for that PY prior to its start (that is on or before June 30, 2021 for PY1 and on or before December 31 of the prior PY in which the opt-out would occur for PY2-PY5. A new entity that furnished less than 20 episodes or no episodes at all across the randomly selected CBSA during the period used to assess opt-out eligibility (2019 for PY1, 2020 for PY2, and so on) will qualify for the low volume opt-out for a particular PY. Entities must attest to the intention of opting out of the Model prior to the start of the applicable PY.

**38. I am a radiation oncologist. Can I opt in to participate in the RO Model if I am not in a selected Core-Based Statistical Area (CBSA)?**

No. An individual, physician group practice (PGP), or facility that is not located in one of the selected CBSA may not opt into the RO Model.

**39. What can RT providers and RT suppliers not in the RO Model expect?**

If your ZIP Code is not included in the RO Model, you will not be responsible for following RO Model requirements. You may be randomly selected to be included in the comparison group for the evaluation of the Model. If your ZIP Code is randomly selected to be in the comparison group, all needed information will be pulled from existing Medicare fee-for-service claims you regularly submit and results will be reported in aggregate to help better estimate the impact of the RO Model. We anticipate sending the voluntary CAHPS Cancer Survey to a subset of patients treated by selected comparison group RT providers and RT suppliers to better measure the patient experience of care among RO Model participants. This process will likely be completed twice during the Model performance period.

**40. What if my organization furnishes both professional and technical RT services?**

Freestanding radiation therapy centers, which commonly furnish both the professional and technical components of RT services, are categorized as Dual Participants, and are identified by a single Tax Identification Number (TIN) under the RO Model.

**41. [NEW] A radiotherapy service location shares a TIN with another service location(s). How does this impact their involvement in the RO Model, such as the aggregate quality scores (AQS) or historical experience and case mix adjustments?**

Under the RO Model, participation is determined at the CMS Certification Number (CCN) or Tax Identification Number (TIN) level. If there are multiple service locations or multiple practices furnishing RT services under that a single CCN or TIN, they are considered a single RO participant under the RO Model with data from that TIN or CCN determining historical experience and case mix adjustments, low volume opt-out eligibility, and aggregate quality scores (AQS) for each location. Of note, quality measure reporting is limited to the TIN/NPI combination of participating radiation oncologists, as discussed in other sections of this document.

**42. Can an RO participant be in another CMS payment model and participate in the Radiation Oncology (RO) Model?**

In some cases, you may participate in the RO Model concurrently with other CMS models. Because the RO Model is an episode-based payment initiative, RT providers and RT suppliers participating in the RO Model will not be precluded from also participating in an ACO initiative. Specifically, overlap is possible in two instances: (1) the same RT provider or RT supplier participates in both a Medicare ACO initiative and the RO Model; or (2) a beneficiary that is aligned to an ACO participating in a Medicare ACO initiative receives care from a RT provider or RT supplier outside the ACO that is participating in the RO Model. It is possible that certain shared savings payments made under ACO initiatives may overlap with discounts and withholds in the RO Model. CMS will continue to review the potential overlap between the RO Model and ACO initiatives. For more information on potentially duplicative billing, consult the CMS staff responsible for demonstration initiatives.

RO participants may also participate in the Oncology Care Model (OCM) while participating in the RO Model. Since prospective episode payments made under the RO Model will not be affected by OCM, OCM will account for RO Model overlap in its reconciliation calculations, and OCM participants will be notified and provided with further information through OCM's typical channels of communication. Finally, there may be overlap with the Bundled Payments for Care Improvement (BPCI) Advanced Model. While there are no cancer episodes included in the design of BPCI Advanced, a beneficiary in an RO episode could be treated by a provider or supplier that is participating in BPCI Advanced for one of the eight Clinical Episode Service Line Groups that group the 34 Clinical Episodes included in BPCI Advanced. Since prospective episode payments made under the RO Model will not be affected by BPCI Advanced, BPCI Advanced will determine whether to account for beneficiary overlap with the RO Model in its Reconciliation calculations, and BPCI Advanced Participants will receive further information from CMS if the BPCI Advanced Model team determines to make changes to their overlap policy.

The RO Model does not include RT providers and RT suppliers that only furnish RT services in Maryland and Vermont to avoid overlap between the RO Model and participants in the Maryland Total Cost of Care Model and the Vermont All-Payer ACO Model, respectively. The RO Model also does not include hospital outpatient departments (HOPDs) that participate in, or identified as eligible to participate in, the Pennsylvania Rural Health Model.

**43. Can I still participate in the RO Model if I leave my current physician group practice (PGP) and join another one?**

Yes, but only if your new PGP is an RO participant, i.e. is furnishing RT services in one of the Core-Based Statistical Areas (CBSAs) randomly selected to participate in the RO Model. RO participants must supply and/or confirm the National Provider Identifiers (NPIs) for the physicians who bill using the applicable Taxpayer Identification Number (TINs), and annually attest to the accuracy of an individual practitioner list provided by CMS, of all of the eligible clinicians who furnish care under the RO participant's TIN. RO participants must notify the Innovation Center of changes in business or billing arrangements through the Radiation Oncology Administrative Portal (ROAP).

**44. What happens if my current physician group practice (PGP) changes the hospital outpatient department (HOPD) or freestanding radiation therapy center where it furnishes the Professional component of RT services?**

If the PGP changes the facility where they furnishes professional RT services, it will continue to participate in the RO Model if the RO beneficiary continues to receive the technical component of RT services at a facility that is an RO participant. If each facility where the PGP will now furnish professional RT services is not a participant in the RO Model, then the PGP will no longer participate in the RO Model. Conversely, if a PGP furnishes professional RT services in more than one facility, and at least one of those facilities is a participant in the RO Model, then the PGP will continue to participate in the RO Model.

**45. What happens if a facility that furnishes the Technical component of RT services terminates its relationship with a participating physician group practice (PGP)?**

If a facility that furnishes the Technical component of RT services terminates its relationship with a participating PGP, then it may continue in the Model as long as it establishes a relationship with a new PGP that furnishes the Professional component of the RT services. Participants must notify CMS of changes in business or billing arrangements in accordance with our regulations at 42 CFR 512.180(c), Notice of change in control and 42 CFR 512.260(a), Reassignment of billing rights.

## RO Participant Requirements

**46. [REVISED] What must RO participants do to meet the RO Model participation requirements?**

In addition to meeting Medicare eligibility requirements, RO participants must meet additional requirements, including:

- Notify beneficiaries of participation in the RO Model
- Discuss with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under the RO Model
- Starting in PY2 on January 1, 2022, use a Certified Electronic Health Record Technology (CEHRT) throughout the performance year (PY) in a manner sufficient to meet applicable requirements of the Advanced APM criteria codified in § 414.1415(a)(1)(i).
- Submit claims in accordance with the RO Model billing instructions
- Submit data on quality measures (QM) through the RO Model Secure Data Portal by the following March of each PY, and clinical data elements (CDE) in July and January of each PY (or forfeit the potential to earn back all or some of the quality withhold amount)

- Ensure all individual practitioners:
  - Discuss goals of care with each RO beneficiary before initiating treatment and communicate to the RO beneficiary whether the treatment intent is curative or palliative
  - Adhere to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or, alternatively, document in the medical record the extent of and rationale for any departure from these guidelines
  - Assess each RO beneficiary's tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses
  - Assess the RO beneficiary's performance status as a quantitative measure determined by the physician
  - Send a treatment summary to each RO beneficiary's referring physician within 3 months of the end of treatment to coordinate care
  - Perform and document Peer Review (audit and feedback on treatment plans) for 50 percent of new patients in PY1, for 55 percent of new patients in PY2, for 60 percent of new patients in PY3, for 65 percent of new patients in PY4, and for 70 percent of new patients in PY5 preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment.
- Finally, at such times and in the form and manner specified on the Radiation Oncology Administrative Portal (ROAP), each Technical participant and Dual participant must annually attest to whether it actively participates with a AHRQ-listed patient safety organization (PSO) (for example, by maintaining a contractual or similar relationship with a PSO for the receipt and review of patient safety work product).

**47. [REVISED] What happens if I am not compliant with RO Model participation requirements?**

If the RO Participant is non-compliant with the RO Model participation requirements, there are various options for dealing with this in accordance with the remedial action section, set forth in § 512.160 of the Final Rule. RO participants must satisfy the requirements in § 512.220 to qualify for the APM Incentive Payment.

**48. How should RO participants notify beneficiaries that they are included in the RO Model?**

RO participants are required to notify beneficiaries with a beneficiary notification letter (available on the RO Model website, <https://innovation.cms.gov/media/document/ro-bene-notif-letter>) during the initial treatment planning session which will detail, among other things, the RO beneficiary's right to refuse having his or her Medicare claims data shared with the RO participant for care coordination and quality improvement purposes.

**49. [NEW] What are the requirements for the peer review process?**

Participants must perform and document Peer Review (audit and feedback on treatment plans) for:

- 50 percent of new patients in PY1,
- 55 percent of new patients in PY2,
- 60 percent of new patients in PY3,
- 65 percent of new patients in PY4, and

- 70 percent of new patients in PY5.

Peer review should occur preferably before starting treatment, but in all cases before 25 percent of the total prescribed dose has been delivered and within 2 weeks of the start of treatment (85 FR 61369).

#### **50. [NEW] How do I implement peer review?**

The RO Model does not specify how an RO participant shall implement Peer Review (85 FR 61369), other than the requirements listed in the question “What are the requirements for the peer review process”. The RO participant may choose how they document compliance with the Peer Review requirement.

RO participants may seek advice from their professional organizations and their peers.

## **Beneficiary Eligibility**

### **51. Which Medicare beneficiaries are included in the RO Model?**

A Medicare beneficiary who meets the following criteria will be included in the RO Model:

- Receives included RT services in a five-digit ZIP Code linked to a selected CBSA from an RO participant that billed the start of episode (SOE) modifier for the PC or TC of an RO episode during the Model performance period for one of the 16 included cancer types.
- At the time that initial treatment planning service of the episode is furnished by an RO participant, the individual:
  - Is eligible for Medicare Part A and enrolled in Medicare Part B.
  - Has traditional Medicare FFS as his or her primary payer (i.e. is not enrolled in a PACE plan, Medicare advantage or another managed care plan, or is not covered under United Mine Workers insurance).
  - Is not in a Medicare hospice benefit period.

In other words, beneficiaries with Medicaid or Medicare Advantage as their primary payer will not be included in the Model and should continue to be billed as usual.

Beneficiaries enrolled in a clinical trial for RT services for which Medicare pays routine costs will also be included in the RO Model if the above criteria apply.

### **52. Can beneficiaries enrolled in qualifying, federally funded clinical trials be included in the RO Model?**

Beneficiaries that meet all the inclusion criteria at 42 CFR 512.215(a) and are enrolled in a clinical trial for which Medicare pays routine costs will be included in the RO Model in accordance with 42 CFR 512.215(b).

### **53. What is the billing process for a beneficiary in a qualifying, federally funded clinical trial?**

CMS will rely on RO participants to determine if the beneficiary is enrolled in a qualifying clinical trial. If so, they will use the existing claims process for billing CMS for clinical trials in addition to adding the appropriate modifier or condition code to allow the claim to be paid fee-for-service. CMS will monitor this aspect of the RO Model closely to ensure these claims are valid and beneficiaries are protected.

**54. [NEW] If a center has patients participating in a qualifying, federally funded clinical trial, is the whole center exempt or just those patients?**

Only patients receiving included RT services for one of the included cancer types that are in a qualifying clinical trial are exempt from the bundled payment. RO participants should add the existing modifiers for clinical trials to identify these patients. The RO Model team plans to monitor these claims. The current Medicare policy is described in Routine Costs in Clinical Trials 100–3 section 310.1.

**55. Can beneficiaries continue to choose their RT providers and/or RT suppliers under the RO Model?**

Beneficiaries continue to have the freedom to choose their providers and/or suppliers under the RO Model. The RO Model does not restrict beneficiaries' ability to choose to receive care from any provider or supplier. RO participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose to receive care from any provider or supplier or from any health care provider who has opted out of Medicare. RO participants may communicate to RO beneficiaries the benefits of receiving care with the RO participant, if otherwise consistent with the requirements of the RO Model and applicable law.

**56. Can beneficiaries opt out of the Radiation Oncology (RO) Model?**

No, beneficiaries may not opt out of the RO Model if they receive RT services from an RO participant. However, beneficiaries may elect to see a RT provider and/or RT supplier who is not participating in the RO Model.

**57. Will beneficiaries be notified of their RT providers' and/or RT suppliers' participation in the RO Model?**

CMS recognizes the importance of informing beneficiaries that their RT providers and/or RT suppliers are participating in the RO Model. Therefore, Professional participants and Dual participants must provide an RO Model Beneficiary Notification Letter, at <https://innovation.cms.gov/media/document/ro-bene-notif-letter>, to Medicare beneficiaries receiving treatment from them.

**58. What if an RO beneficiary switches RT providers or RT suppliers? Does the RO participant keep the episode payment amount for RT services furnished?**

In the event that an RO beneficiary switches RT provider or RT supplier after the start of episode (SOE) claim has been paid, CMS will subtract the first episode payment paid to the RO participant from the FFS payments owed to the RO participant for services furnished to the beneficiary before the transition occurred and listed on the no-pay claims. This will occur during the annual reconciliation process.

**59. How will the RO Model impact beneficiary cost-sharing?**

All the standard rules and regulations under fee-for-service (FFS) pertaining to beneficiary coinsurance apply under the RO Model, including the Medicare bad debt provision. Beneficiaries will be responsible for 20 percent coinsurance of the prospective episode payments made under the RO Model (the exception is beneficiaries who experience an incomplete episode or duplicate services; see next question). Because CMS will apply a discount to episode components, we expect that beneficiary cost-sharing will be, on average, lower relative to what typically would be paid under Medicare's FFS system. As with all Innovation Center models, CMS will monitor the RO Model for any unintended consequences that might negatively impact RO beneficiaries.

**60. How will an incomplete episode or a duplicate RT service affect beneficiary cost-sharing?**

For duplicate RT services, a beneficiary will be responsible for 20 percent of the fee-for-service (FFS) amount for RT services furnished by the RT provider and/or RT supplier for one or more duplicate RT services. For incomplete episodes, a beneficiary will be responsible for 20 percent of the FFS amounts that would have been paid in the absence of the RO Model, except when the RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided that an RT provider or RT supplier furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service. In this case, the beneficiary coinsurance payment equals 20 percent of the first installment of the episode payment amount to be paid to the RO participant(s). If an RO participant bills the Model-specific HCPCS code and EOE modifier prior to the date that the RO beneficiary ceases to have traditional FFS Medicare, then the beneficiary coinsurance payment equals 20 percent of the full episode payment amount for the PC or TC. *Please refer to questions related to incomplete episodes and duplicate services.*

**61. Where can beneficiaries go with questions?**

Beneficiaries with questions or who feel their care has been compromised can call 1-800-MEDICARE or contact their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs). Local BFCC-QIO contact information can be located here: <https://www.qioprogram.org/locate-your-qio>

## RO Episode Design Details

**62. Which types of cancer diagnoses are included in the RO Model?**

There are 16 cancer types included in the model.

1. Anal Cancer
2. Bladder Cancer
3. Bone Metastases
4. Brain Metastases
5. Breast Cancer
6. Cervical Cancer
7. CNS Tumors
8. Colorectal Cancer
9. Head and Neck Cancer
10. Liver Cancer
11. Lung Cancer
12. Lymphoma
13. Pancreatic Cancer
14. Prostate Cancer
15. Upper GI Cancer
16. Uterine Cancer

Any addition to, or removal of, a cancer type from this list will be communicated via the RO Model website and in written correspondence to RO participants. CMS will notify RO participants of any changes to the diagnosis codes for the included cancer types per the CMS standard process for announcing coding changes and update the list on the RO Model website no later than 30 days prior to each performance year.

For current diagnosis and billing codes, you may reference the Final Rule for the ICD-10 (Table 1) [85 FR 61158] and HCPCS codes (Table 2) [85 FR 61166].

### **63. What is the length and timing of an RO episode?**

RO episodes are 90 days long. Day 1 is considered the date that a Professional participant or Dual participant furnishes the initial treatment planning service to an RO beneficiary, provided that a Technical participant or Dual participant furnishes an RT delivery service within 28 days of the treatment planning service. Once an episode is initiated, RO participants are responsible for all the RT service needs of the beneficiary during the 90-day episode period. If, however, a Technical participant or Dual participant does not furnish the TC to an RO beneficiary within 28 days of the initial treatment planning service, this is considered an incomplete episode.

### **64. When does an RO episode end?**

An RO episode ends when all RT services have been furnished and both the Professional participant and the Technical participant have submitted a billing claim with the “End of Episode” (EOE) modifier. An RO episode cannot be longer than 90 days (i.e. 89 days after the “start” of the episode, which is the date of service that the initial treatment planning service was rendered, and a claim submitted with the “Start of Episode” (SOE) modifier). While the RO episode can be as long as 90 days, an EOE claim can be submitted and paid as early as day 28 of the 90-day episode if the RO participant, to the best of their knowledge, is certain that the treatment plan is complete. Any RT services furnished after the EOE claim is submitted will not be paid separately during the remainder of the RO episode. We will monitor the Medicare claims system to identify potentially adverse changes in referral, practice, or treatment delivery patterns and subsequent billing patterns.

### **65. What RT services are included in the RO Model?**

The RO episode covers most RT services furnished in HOPDs and freestanding radiation therapy centers, including treatment planning, certain technical preparation and special services, treatment delivery, and treatment management. For these services only, the RO Model payments will replace current Medicare FFS payments. A complete list of Healthcare Common Procedure Coding System (HCPCS) codes that represent treatment planning, technical preparation and special services, treatment delivery, and treatment management for the included modalities are provided in the Final Rule (85 FR 61114), in the RO Model Billing Guide, and maintained on the RO Model website. We will notify RO participants of any changes to the HCPCS codes per the CMS annual Level 2 HCPCS code file. All RT services furnished by an RO participant during the Model performance period, but not included in the list of included RT services, will be subject to Medicare FFS payment rules.

### **66. What RT modalities are included in the RO Model?**

The following RT modalities are included in the RO Model: various types of external beam RT including 3-dimensional conformal radiotherapy (3DCRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT) and proton beam therapy (PBT); image-guided radiation therapy (IGRT); and

brachytherapy. These modalities are the most commonly used to treat the 16 included cancer types and including these modalities will provide CMS with greater visibility into the ability of an episode payment model to affect patients' care, experience, and overall system costs. Excluded modalities include certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. We excluded these services from the Model because they are not offered in sufficient amounts for purposes of evaluation.

#### **67. Why is Proton Beam Therapy (PBT) included in the RO Model?**

PBT is included in the RO Model because the Model is designed, in part, to evaluate the efficacy of site neutral payments and modality agnostic payments for RT services. There has been debate regarding the benefits of PBT relative to other, less expensive modalities. The Institute for Clinical and Economic Review (ICER) evaluated the evidence of the overall net health benefit (which takes into account clinical effectiveness and potential harms) of PBT in comparison with its major treatment alternatives for various types of cancer.<sup>1</sup> ICER concluded that PBT has superior net health benefit for ocular tumors and incremental net health benefit for adult brain and spinal tumors and pediatric cancers. ICER judged that PBT is comparable with alternative treatments for prostate, lung, and liver cancer, although the strength of evidence was low for these conditions. In a June 2018 Report to Congress, MedPAC discussed Medicare coverage policy and use of low-value care and examined services, including PBT, which lack evidence of comparative clinical effectiveness and are therefore potentially low value.<sup>2</sup> MedPAC concluded that there are many policy tools, including new payment models, that CMS could consider adopting to reduce the use of low-value services. Given the continued debate around the benefits of PBT, and understanding that the PBT is more costly, we believe that it is appropriate to include in the RO Model's test.

#### **68. What if the RO beneficiary needs additional RT services beyond the 90 days?**

Another episode may not be triggered until at least 28 days after the previous episode has ended. This is because, while a missed week of treatment is not uncommon, a break from RT services for more four weeks (or 28 days) generally signals the start of a new course of treatment.<sup>3</sup> We refer to the 28-day period after an episode has ended, during which time an RO participant will bill for medically necessary RT services furnished to an RO beneficiary in accordance with Medicare FFS billing rules, as the "clean period." If clinically appropriate, an RO participant may initiate another episode for the same beneficiary after the 28-day clean period has ended. CMS will closely monitor utilization of RT services following the 90-day period and the initiation of multiple episodes for a single beneficiary.

#### **69. What is an incomplete episode?**

An incomplete episode may occur for different reasons:

- 1) A Technical participant or a Dual participant does not furnish a technical component to an RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing the initial RT treatment planning service to that RO beneficiary;

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<sup>1</sup> Ollendorf, D. A., J. A. Colby, and S. D. Pearson. 2014. Proton beam therapy. Report prepared by the Institute for Clinical and Economic Review for the Health Technology Assessment Program, Washington State Health Care Authority. Olympia, WA: Washington State Health Care Authority. [https://icer-review.org/wp-content/uploads/2014/07/pbt\\_final\\_report\\_040114.pdf](https://icer-review.org/wp-content/uploads/2014/07/pbt_final_report_040114.pdf).

<sup>2</sup> [http://medpac.gov/docs/default-source/reports/jun18\\_ch10\\_medpacreport\\_sec.pdf](http://medpac.gov/docs/default-source/reports/jun18_ch10_medpacreport_sec.pdf)

<sup>3</sup> CMS was advised by radiation oncologists consulting on the design of the Model that four weeks signals the start of a new course of treatment.

- 2) Traditional Medicare stops being the primary payer for the RO beneficiary at any point during the relevant 90-day period, provided that an RT provider or RT supplier furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service; or
- 3) An RO beneficiary switches RT provider or RT supplier before all RT services in the episode have been furnished.

Incomplete episodes are reconciled to fee-for-service during the annual reconciliation process or true-up process except when an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and EOE modifier, provided an RO participant furnishes a technical component RT service to the RO beneficiary within 28 days of such initial treatment planning service. In this case, the RO participant is owed only the first installment of the episode payment amount.

**70. [NEW] What is an example of an incomplete episode?**

There are three types of incomplete episodes. First, an episode is considered incomplete if a Technical participant or Dual participant does not furnish a technical component to a beneficiary within 28 days following a Professional participant or Dual participant furnishing the initial RT treatment planning service to that beneficiary. If all RT services are furnished to a beneficiary in a non-participating ZIP Code, even if the initial RT treatment planning service were furnished in a participating ZIP Code, the episode would be incomplete. Second, an episode is considered incomplete if the beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and an EOE modifier. For example, this could occur if a beneficiary switches to Medicare Advantage or a private payer during the episode. Third, an episode is considered incomplete if a beneficiary switches RT provider or RT supplier during the episode and is no longer under the care of the participant that initiated the PC and/or the TC of the episode.

**71. What is a duplicate radiotherapy (RT) service?**

A duplicate RT service is defined as any included RT service that is furnished to an RO beneficiary by an RT provider or RT supplier that is not excluded from participation in the RO Model, and that did not initiate the PC or TC of the RO beneficiary's RO episode.

An RT service furnished to a single RO beneficiary by a RT provider or RT supplier not operating in an included CBSA, but not otherwise excluded from participation in the Model, is considered a duplicate RT service.

An RT service furnished to a single RO beneficiary by a RT provider or RT supplier operating in an included CBSA but excluded from participation in the Model is not considered a duplicate RT service.

The RO beneficiary would remain under the care of the RO participant that initiated the PC and/or TC, and in many circumstances, the duplicate RT service would be a different modality than what is furnished by the RO participant. The RO participant(s) that bills the SOE and EOE claims would receive the bundled payment and the RT provider and/or RT supplier furnishing one or more duplicate RT services would bill claims using the designated modifier or condition code to indicate that they should be paid FFS. Thus, cash flow would not be affected by this.

**72. [NEW] What is an example of a duplicate radiotherapy (RT) service?**

A duplicate RT service is any included RT service that is furnished to an RO beneficiary by an RT provider or RT supplier that did not initiate the PC or TC of that beneficiary's RO episode. The RT service is a duplicate RT service even if the RT provider or RT supplier did not furnish the included RT service in a participating ZIP Code. The RT service is not a duplicate RT service if it is furnished in Maryland, Vermont, or in a U.S. Territory. The RT service is also not a duplicate RT service if it is furnished by an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital or an entity identified by CMS as eligible to participate in the Pennsylvania Rural Health Model.

Duplicate RT services could occur when separate RT providers and RT suppliers deliver a combination of modalities like EBRT and brachytherapy to an RO beneficiary. Any included RT service that is considered covered by the bundled payment provided by an additional RT provider or RT supplier is a duplicate service.

**73. How will the RO Model payment method impact providers that were over-using conventional fractionalization versus those using appropriate rates of hypofractionation?**

It is not CMS' intent to encourage hypofractionation specifically. It is our intent to use hypofractionation as an example of a treatment option often cited in nationally recognized, evidence-based guidelines. We rely on Medicare providers and suppliers to furnish appropriate care to our beneficiaries. As finalized in section III.C.14 and III.C.16, we will monitor for unintended consequences of the RO Model, and such monitoring could include utilization patterns regarding fractions.

Some RO participants expressed concern that efficient practices will be punished under the RO Model. We do not believe that is the case. We calculate episode-based payments under the RO Model based on the average spend for each episode in all HOPDs nationally. If RO participants spent less historically (on average) than the average spending of all HOPDs nationally, then their payment amount is 90 percent of what they would have been paid historically for the PC and/or TC of the respective cancer type furnished and 10 percent of the corresponding national base rate. This will result in a historically efficient RO participant seeing an increase in payment compared to historical amounts prior to the discount and withholds being applied; for some of these RO participants, the payment amounts will be an increase under the Model even with the discount and withholds being applied.

**74. How will the RO Model account for new technology?**

To the extent that new technologies and new equipment are billed under new HCPCS codes, we will go through rulemaking to propose adding those new codes to the list of RO Model Bundled HCPCS list. We believe that any increased utilization of established codes that are included RT services over time will be accounted for with the trend factor described in section III.C.6.d. Until new technologies with corresponding HCPCS codes are added to the list of included services for the RO Model, they will be paid fee-for-service.

## Participant Billing and Reimbursement

### **75. How often will payments be made to RO participants?**

RO episodes are paid in two installments: one tied to when the episode begins, and another tied to when the episode ends. A Professional participant will receive two installment payments for furnishing the Professional component (PC) of an episode, a Technical participant will receive two installment payments for furnishing the TC of an episode, and a Dual participant will receive two installment payments for furnishing the PC and TC of an episode which can be included on the same claim. Splitting episode payment amounts into Professional components and Technical components allows for the use of current claims systems for PFS and OPFS to adjudicate RO Model claims and reduces burden on RO participants. In order to receive payment, RO participants are required to bill an RO Model-specific HCPCS code and a modifier indicating the start of an episode (V1) and the end of an episode (V2).

### **76. How will RO participants submit claims and be reimbursed for RT services furnished to RO beneficiaries under the RO Model?**

RO episodes will span a 90-day period, initiated on the date of service when the initial treatment planning service is furnished and subsequent billing of a professional RO Model-specific HCPCS code with a start of episode (SOE) modifier (V1). At that point, CMS will make a prospective lump sum payment for the first half of the payment using the existing CMS claims processing systems to participants. Upon submission of a claim with an RO Model-specific HCPCS codes and end of episode (EOE) modifier (V2), CMS will pay the second half of the payment (the EOE claim can be submitted as early as day 28 of the episode as long as the RO participant is certain to the best of their ability that no further RT services will be required within this 90-day episode). These payments will cover RT services (excluding duplicate services) furnished by the RO participant during the 90-day period for the RO beneficiary. Participants cannot bill another 90-day episode for another 28 days after a V2 EOE modifier claim has been filed and all services will be billed FFS as needed during that time.

Participants will use a set of new, RO Model-specific, Healthcare Common Procedure Coding System (HCPCS) codes to bill for the 90-day prospective episode payments. The Innovation Center developed 32 unique HCPCS codes (one professional component code and one technical component code for each of the 16 cancer types included in the Model). While separate payments will be made for the professional and technical component, each component is part of a single episode.

### **77. How will RO participants submit claims under the RO Model?**

Professional participants and Dual participants that furnish the Professional Component (PC) of an episode are required to bill a new RO Model-specific HCPCS code and a V1 [Start of Episode (SOE)] modifier that indicates the treatment planning service has been furnished.

- The first half of the payment for the PC of the episode is made through the PFS and will only be paid to physicians (as identified by their respective TINs) after submission of the claim.
- To receive the second half of the payment, a Professional participant or Dual participant must bill the same RO Model-specific HCPCS code that initiated the episode with a V2 [End of Episode (EOE)] modifier.
- The same RO Model-specific HCPCS code with a V2 modifier may be submitted by the Professional participant as early as day 28 of the 90-day episode if the RO participant, to the best of their knowledge, is certain that the treatment plan is complete instead of waiting for 90 days to elapse.

- Any RT services furnished after the EOE claim is submitted will not be paid separately during the remainder of the 90-day RO episode.

Technical participants and Dual participants that furnish the Technical Component (TC) of an episode are required to bill a new RO Model-specific HCPCS code with a V1 [Start of Episode (SOE)] modifier for the first half of the payment.

- The first half of the payment for the TC of the episode will only be paid to HOPDs (via the OPPS) or FRTCs (via the PFS) after submission of the claim.
- The TC of the episode will begin on or after the date that the PC of the episode is initiated and will last until the PC of the episode concludes.
- The Professional participant will provide the Technical participant with a signed and dated radiation prescription and the final treatment plan, all of which is usually done electronically. This will inform the Technical participant of when the episode began and allowing them to determine the date for the EOE. The submission and payment of TC claims is not dependent on the submission of PC claims. If the TC claim with the SOE modifier is received first, the claims system will estimate the first day of the episode. A similar process will occur for EOE claims.

To receive the second half of the payment, a Technical participant or Dual participant must bill the same RO Model-specific HCPCS code that initiated the episode with a V2 [End of Episode (EOE)] modifier.

- The RO Model-specific HCPCS code with a V2 EOE modifier may be submitted by the Technical participant or the Dual participant as early as day 28 of the 90-day episode if the RO participant, to the best of their knowledge, is certain that the treatment plan is complete instead of waiting for 90 days to elapse.
- Any RT services furnished after the EOE claim is submitted will not be paid separately during the remainder of the RO episode.

**78. Will payments be different for each provider in a physician group practice (PGP)?**

No. Payment is made to RO participants at the Model ID level (the PGPs TIN).

**79. Does an RO participant have to submit any other claims beyond the Start of Episode and End of Episode claims?**

In addition to the two claims described in the preceding questions, all RO participants (Professional participants, Technical participants, and Dual participants) must submit encounter data (no-pay) claims that include all RT services identified on the RO Model Bundled HCPCS Codes list (included in the Final Rule, on the RO Model website, and in the RO Model Billing Guide) as services are furnished that would outside of the Model be billed under the Medicare FFS systems. The encounter data will be used for evaluation and Model monitoring, specifically trending utilization of RT services, and other CMS research.

**80. What if my patients need services that are not included in the RO Model?**

Beneficiaries included in the RO Model can continue to receive any other medically necessary services that they require. Services not included in the RO Model payment will be billed for and paid under the existing Medicare FFS payment systems.

**81. [NEW] How will ICD-10 codes not in the Model be treated during the RO episode?**

RT services furnished to beneficiaries with ICD-10 codes not included in the RO Model will continue to be paid fee-for-service.

**82. Will upcoming instructions to RO participants include instructions to post gross charges for individual RT services per their chargemasters to beneficiary accounts?**

The RO Model does not instruct hospitals how to post gross charges or apply any other accounting procedures.

## Episode Payment Amount

**83. Are historical experience and case mix adjustments calculated by cancer site?**

No. The participant-specific historical experience and case mix adjustments do not vary by cancer type. There is one professional and/or one technical case mix adjustment per RO participant depending on the type of component the RO participant furnished during the 2016-2018 period, just as there is one professional and/or one technical historical experience adjustment per RO participant, depending on the type of component the RO Participant furnished during the 2016-2018 period.

**84. How does opting out impact my historical experience adjustments in later performance years?**

Opting out does not impact an RO participant's historical experience adjustment. Whether a participant opts-out or not, a historical experience adjustment will still be calculated based on 2016 – 2018 episodes and used if an RO participant does not opt-out in later performance years.

**85. How are the 60 episodes for the historical experience adjustment calculated?**

If you have fewer than 60 episodes in 2016-2018, then you will not get a historical experience adjustment. The 60 episodes are calculated by summing the total over the three-year period. For example, if you have one episode in 2016, 20 in 2017, and 20 in 2018, then you will not get a historical experience adjustment.

**86. Will I be able to find out how much I will be paid before participating in the RO Model?**

In [Table 3](#) of the Final Rule, you will find the national base rates by cancer type. No later than thirty (30) days prior to the start of each performance year, CMS will provide each RO participant with its case mix and historical experience adjustments for both the professional component and technical component on the Radiation Oncology Administrative Portal (ROAP), and the trended national base rates on the RO Model website. The geographic adjustments will be applied in the same manner under the RO Model as they are under FFS in the current PFS and OPFS claims systems. Table 8 and Table 9 of the Final Rule shows how to calculate participant-specific professional episode payment and participant-specific technical episode payment for an episode of a particular cancer type.

**87. What if I have questions about my case mix and historical experience adjustments?**

If an RO participant has questions about the values of their case mix adjustments and/or their historical experience adjustments, they may reach out to the RO Model Help Desk. Please also note that RO participants may download and submit a Data Request and Attestation (DRA) form via the Radiation Oncology Administration Portal (ROAP) to receive different types of files from CMS, including certain

beneficiary line-level claims data, episode-level data, and participant-level data so long as the RO participant uses such data for care coordination and quality improvement purposes.

**88. Does the RO Model have a stop-loss policy?**

RO participants that have fewer than 60 episodes in the baseline period do not have sufficient historical volume to calculate a reliable adjustment. Since these participants do not qualify to receive an historical experience adjustment and may see greater increases or reductions as compared to what they were historically paid under FFS as a result of not receiving the adjustment, we finalized a stop-loss limit of 20 percent for these RO participants that have fewer than 60 episodes in the baseline period and were furnishing included RT services at the time of the effective date of the final rule in the CBSAs selected for participation. Using no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the Model, CMS will 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 are determined at the time of reconciliation.

**89. Is the stop-loss amount based on what the RO participant would have been paid under fee-for-service, taking into consideration the site of service?**

Yes. The stop-loss limit is based on what the RO participant would have been paid under fee-for-service, taking site of service into consideration.

**90. Why is the base rate for liver cancer lower in the final rule?**

As noted in Section III.C.5.c of the final rule, CMS removed Yttrium-90 from the RT services included on the list referred to as “RO Model Bundled HCPCS”. The changes to the included HCPCS codes had an impact on the final base rates for some cancer types.

## Reconciliation Process

**91. What is the purpose of the annual reconciliation process?**

An annual reconciliation will be conducted for each RO participant after each PY to calculate payments due to the RO participant and payments owed to CMS under the withhold policies. The annual reconciliation will occur in August following each PY to allow time for claims run-out, data collection, reporting, and calculating results. For example: The annual reconciliation for PY1 will occur in August of 2022. The reconciliation process includes a review of incomplete episodes and duplicate RT services and any stop-loss reconciliation amount due. Under the reconciliation process, CMS will calculate the amount of the quality and patient experience withholds RO participants earn back based on clinical data reporting, and reporting and performance on quality measures, and the beneficiary-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Radiation Therapy Survey. Any portion of the withholds that is earned back will be distributed in an annual lump sum after the reconciliation process.

When an RO participant owes CMS money (reconciliation repayment) or CMS owes the RO participant money (reconciliation payment), the RO participant shall not collect coinsurance on these amounts. We will provide RO participants with additional instructions for billing, particularly as it pertains to how beneficiary coinsurance will be accounted for in reconciliation.

## **92. What if I disagree with my RO Model Reconciliation Report?**

Participants may submit a request to [RadiationTherapy@cms.hhs.gov](mailto:RadiationTherapy@cms.hhs.gov) if they detect calculations error(s) on an RO Model reconciliation report that has not been deemed final. There is a two-level process for RO participants to request reconsideration of determinations related to calculation of their reconciliation payment, recoupment amount, or AQS under the RO Model. First, participants must use the *timely error notice process* and if a second review is required, they may use the *reconsideration review process*. The RO Model pricing methodology and Aggregate Quality Score methodology are not subject to review.

## **Quality Measures**

### **93. [REVISED] Will the RO Model collect quality measure data?**

Yes. The RO Model will collect quality measure data for two reasons. First, the RO Model is designed to preserve or enhance quality of care, and quality measures are necessary to quantify the impact of the RO Model on quality of care, RT services and processes, outcomes, patient experience, and organizational structures and systems. Second, the RO Model qualifies as an Advanced APM, and will also meet the MIPS APM criteria, starting in performance year (PY 2). We selected the RO Model's quality measures to satisfy concurrently the quality measure-related requirements for both an Advanced APM and a MIPS APM. Quality data collection will begin in PY2. Quality data is gathered at the Model ID level not the beneficiary level.

### **94. [REVISED] What quality measures are included in the RO Model?**

The following four quality measures are included in the RO Model:

- Oncology: Medical and Radiation - Plan of Care for Pain -*NQF #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*
- Treatment Summary Communication – Radiation Oncology

Oncology: Medical and Radiation – Plan of Care for Pain; Preventive Care and Screening: Screening for Depression and Follow-Up Plan; and Advance Care Plan will be implemented as pay-for-performance measures beginning in PY2. Treatment Summary Communication will be implemented as pay-for-reporting in PY2, and as pay-for-performance in PY4 (subject to change depending on availability of a historical benchmark).

Starting in PY3, the RO Model will also include patient experience measures based on the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Cancer Care Radiation Therapy Survey. The specific measures will be proposed through future rulemaking.

### **95. [NEW] Do RO participants have to report on quality measures for cancer types that are not in the Model and are billed fee-for-service?**

Yes. Professional participants and Dual participants should report on all patients seen by a participating radiation oncologist that meet the published inclusion criteria for the measure.

**96. [NEW] Do RO participants have to report on quality measures for patients that do not have traditional Medicare as their primary insurance?**

Yes. Professional participants and Dual participants should report quality measure data for all patients seen by participating radiation oncologists as described in the measure's specification.

**97. Is the RO Model collecting outcome measures?**

No. At the present time CMS is not collecting data on any outcome measures for the RO Model. The Quality Payment Program does require that model participants in Advanced APMs who furnish professional services submit data for at least one outcome-based quality measure, unless CMS determines that there are no available or applicable outcome measures included in the MIPS final quality measures list for the Advanced APM's first Qualifying APM Participant (QP) Performance Period. CMS determined there are currently no outcome measures available or applicable for the RO Model; as such, this outcome measure requirement does not apply to the RO Model. However, if a potentially relevant outcome measure becomes available in the future, CMS will review it to determine if it is appropriate for the RO Model, and if so, propose to apply it to the RO Model through rulemaking.

**98. How will quality measure data be submitted?**

RO participants will use the RO Model Secure Data Portal, and an associated template, that allows Professional participants and Dual participants to input quality measure data. The RO Model template for Professional participants and Dual participants includes the measure specifications for each quality measure, and instructions for how to use the template and the RO Model Secure Data Portal for data submission. The template also includes relevant education and outreach information on the use of these mechanisms for data collection and where to submit the data prior to the first data submission period. More information about data submission is available on the [RO Model website](#).

**99. [REVISED] Is the RO Model collecting clinical data?**

Yes. Starting in Performance Year 2, the RO Model will collect clinical data elements to support 1) clinical monitoring; 2) evaluation of the RO Model; 3) informing possible future refinements to the Model; and 4) possible development and testing of new radiation oncology-specific quality measures.

**100. [REVISED] What clinical data elements are participants required to submit?**

All Professional participants and Dual participants with RO beneficiaries treated for five cancer types – prostate, breast, lung, bone metastases, and brain metastases – will be required to report clinical data. The list of clinical data elements for each cancer type will be available on the [RO Model website](#) prior to Performance Year 1, but in general, these elements may comprise of basic clinical information not available in claims or captured in the proposed quality measures, such as cancer stage, disease involvement, treatment intent, and specific treatment plan information. The collection period for clinical data elements (CDEs) will begin on January 1, 2022. The first submission of the clinical data elements for January 1, 2022 through June 30, 2022 will be due in July 2022.

**101. [REVISED] Will clinical data element submission be supported by electronic health records (EHR)?**

To facilitate data collection, the RO Model will share the clinical data elements and reporting standards with EHR vendors and the radiation oncology specialty societies prior to the start of Performance Year (PY) 1 with reporting required at the start of PY 2. Our goal is to structure data reporting standards to the extent possible so that existing EHRs could be adjusted in anticipation of the first submission period. The first submission period will be due July 2022 for clinical data elements collected January 1, 2022

through June 30, 2022. Such changes may facilitate easier data extraction and reduce the additional reporting burden on providers and may increase the quality and volume of reporting. Providers may also opt to extract the necessary data elements manually.

**102. How will performance on quality measures be connected to payment?**

The RO Model includes an Aggregate Quality Score (AQS). The AQS is calculated based on each Professional participant's and Dual participant's 1) performance on a set of quality measures compared to quality performance benchmarks; 2) reporting of data for the proposed pay-for-reporting measures; and 3) reporting of clinical data elements on applicable RO beneficiaries, with 50 percent of the score based on quality measures components and the other 50 percent on successful reporting of clinical data element. The Professional participant's and Dual participant's performance on both portions of the AQS is then used to calculate points, which are then converted into a percentage. This resulting AQS percentage is applied during the reconciliation process to allow a Professional participant or a Dual participant to earn back a percentage of the quality withhold that was included in the calculation of the episode payment amount.

Starting in PY3, Technical participants will be accountable for patient experience via the patient reported CAHPS® Cancer Care Radiation Therapy survey administered by a CMS contractor.

**103. [NEW] My practice has a variety of clinicians, many that are not radiation oncology practitioners.**

**How does this impact our APM/MIPS status? How does this impact our quality scores?**

The RO Model will collect quality measures using a TIN/NPI combination. This combination should capture the RO participant's TIN and eligible clinicians included on the individual practitioner list (IPL) for the RO Model identified by NPI. We are not requiring patients that are not seen by RO participants to be a part of the quality measure collection. Only eligible clinicians included on the individual practitioner list (IPL) for the RO Model will be considered as Qualifying APM Participants (QPs) or as MIPS eligible clinicians (starting in Performance Year 2). Any other practitioners in a practice not on the IPL for the RO Model would participate in the Quality Payment Program separately.

**104. [NEW] Do we need to submit both question #143 and #144 for the Pain Intensity Quantified quality measure?**

No. 143 and 144 are separate quality measures. CMS is not collecting information on pain scores for all patients. CMS is collecting data specifically on Measure #144 to ensure that patients with moderate to severe pain have a Pain Plan in place.

**105. [NEW] What are the next steps for the clinical data elements (CDEs)?**

We are reviewing comments from the informal request for information (RFI) as they relate to the removal of CDEs.

**106. [REVISED] Will my practice administer the CAHPS® Cancer Care Radiation Therapy Survey?**

No. A CMS contractor will be administering the survey. Due to the delay of the Model, the Survey will be administered starting in October 2021 instead of April 2021.

## Quality Payment Program

### **107. [REVISED] Does the RO Model qualify as an Advanced Alternative Payment Model (APM) or a Merit-based Incentive Payment System APM (MIPS APM) under the Quality Payment Program?**

We expect the RO Model will qualify as both an Advanced APM and a MIPS APM under the CMS Quality Payment Program beginning in performance year (PY) 2 of the RO Model, starting on January 1, 2022. The RO Model will not qualify for an Advance APM or MIPS APM in PY 1 (July 1, 2021 to December 31, 2021).

### **108. Can RO Participants be Qualifying Alternative Payment Model (APM) Participants?**

The RO Model is an Advanced APM and a Merit-based Incentive Payment System (MIPS) APM. As such, eligible clinicians who are Professional participants and Dual participants may potentially become Qualifying APM Participants (QPs) who earn an APM Incentive Payment and are excluded from the MIPS reporting requirements and payment adjustment. Those who are not excluded from MIPS as QPs or Partial QPs will receive a final score and payment adjustment under MIPS, unless otherwise excepted. We believe these aspects of the RO Model as an Advanced APM and a MIPS APM will provide eligible participants with an example of the upside opportunity for high-performing participants under the Model mentioned by the commenters.

### **109. If a practice is already a participant in an Advanced Alternative Payment Model (APM), are they required to drop that participation and report for the RO Model?**

No, we encourage continued participation in multiple APMs.

### **110. How does the Qualifying Alternative Payment Model (APM) Participant (QP) threshold apply to the RO Model?**

In 2021, the QP threshold will change so that to become a QP, eligible clinicians must receive at least 75 percent of their Medicare Part B payments or see at least 50 percent of Medicare patients through an Advanced APM at one of the determination dates during the QP Performance Period.

### **111. [REVISED] How does the Alternative Payment Model (APM) Incentive Payment apply to RO participants?**

Starting in performance year (PY) 2 (January 1, 2022), eligible clinicians who achieve QP status through the RO Model in a QP Performance Period earn an APM Incentive Payment in the corresponding payment year. The APM Incentive Payment is equal to 5 percent of the aggregate payments for the professional component of the episode payment in the calendar year preceding the payment year starting in P Y2. The technical component of the episode payment is not included when calculating the APM Incentive Payment under the RO Model.

### **112. [REVISED] How does the RO Model interact with the Merit-based Incentive Payment System (MIPS)?**

MIPS eligible clinicians (identified by a combination of their Taxpayer Identification Number and National Provider Identifier) will receive positive, neutral, or negative adjustments to their Medicare Part B payments for covered professional services based on their performance on a range of measures and activities during the applicable MIPS performance period. MIPS eligible clinicians that participate in the RO Model, starting in Performance Year (PY)2 of the RO Model, will see the MIPS payment adjustment factors applied to the professional component only of their RO Model claims. RO

participants that meet the Qualifying APM Participant (QP) threshold will be excluded from MIPS reporting and scoring requirements for the applicable MIPS performance period, starting in PY2 of the RO Model.

**113. [NEW] If an RO participant is not compliant with the Advanced APM requirement to use a Certified Electronic Health Record Technology (CEHRT), does it impact their standing in the RO Model, the MIPS program, or the Advanced APM program?**

The use of CEHRT will be a requirement for the RO Model starting in Performance Year 2, which begins on January 1, 2022. In order to be an Advanced APM, an APM must require participants to use CEHRT. The use of CEHRT is also required under the MIPS Promoting Interoperability performance category. RO participants would be monitored for compliance with the RO Model requirements, including CEHRT.

**114. [NEW] Can an RO participant use one system for Certified Electronic Health Record Technology (CEHRT) and a different software system to capture quality measures and clinical data elements?**

For the CEHRT requirement under the Quality Payment Program (QPP), RO participants must use an EHR software system that is certified by the Office of the National Coordinator for Health Information Technology (ONC). For the quality measures and clinical data elements, RO participants may use the software system of their choice.

**115. [NEW] Do both the Professional participants and Technical participants both need to meet Certified Electronic Health Record Technology (CEHRT) requirements?**

Professional participants and Dual participants are required to meet CEHRT requirements.

**116. [NEW] How does the delay impact Advanced Alternative Payment Model (APM) or Merit-based Incentive Payment System APM (MIPS APM) status for 2021? How should providers handle their 2020 and 2021 quality measures and data reporting?**

Due to the RO Model beginning on July 1, 2021, we expect the RO Model will not qualify as an Advanced APM or a MIPS APM until Performance Year 2, starting on January 1, 2022. RO participants who are currently participating in the Quality Payment Program (QPP) for 2020 and 2021 should continue to participate in QPP as they have been. RO participants may receive credit for Improvement Activities. The individual practitioner list will only be used for the Quality Payment Program in PY1 to assign an automatic 50 percent score for the Improvement Activity performance category in MIPS for RO participants. Please see the QPP website at <https://qpp.cms.gov/> for more information.

**117. [NEW] When will the Quality Payment Program (QPP) system recognize RO Model participants?**

Participation in the RO Model will be reflected on the QPP website starting in Performance Year (PY) 1 (participation will be displayed in December 2021). Participants may receive credit for Improvement Activities during PY1.

## Monitoring and Evaluation

### **118. What will RO participants be monitored for to ensure RO Model compliance?**

Pursuant to 512.150(b), CMS will conduct monitoring activities to ensure that each Professional participant, Dual participant, and their individual practitioners are in compliance with the terms of the Model. In addition, CMS may conduct monitoring activities to understand Model participants' use of model-specific payments, to promote the safety of beneficiaries, and to ensure the integrity of the Model.

### **119. What data are RO Participants required to provide for monitoring purposes?**

CMS has broad authority to obtain information for monitoring and oversight. Under § 512.150(b)(2), CMS may use "any relevant data or information, including without limitation all Medicare claims submitted for items or services furnished to model beneficiaries." In conducting monitoring activities, CMS may require the submission of any information determined necessary to monitor the Model (see 42 CFR § 403.1110(b)). Such information may include medical records and other protected health information required to support audits of claims data and quality and clinical data. CMS may use these data to track utilization of certain types of treatments, beneficiary hospitalization and emergency department use, and fractionation (numbers of treatments) against historical treatment patterns for each participant. Site visits may be used to better understand how RO participants manage services, use evidence-based care, and practice patient-centered care. Site visit activities may include, but are not limited to, interviewing RO participant(s) and staff, reviewing records, and observing treatments.

### **120. What is the purpose of the Model evaluation?**

Under section 1115A(b)(4) of the Act, the Model evaluation must include an analysis of at least the following information: (i) the quality of care furnished under the Model, including measurement of patient-level outcomes and appropriate patient-centeredness criteria; and (ii) the changes in Medicare spending under the Model. All RO participants are required to cooperate with efforts to conduct an independent, federally funded evaluation of the Model, which may include participation in surveys, interviews, site visits, and other activities that CMS determines necessary to conduct a comprehensive formative and summative evaluation. The evaluation will assess the impact of the Model in meeting its intended goals and serves to inform policy makers about the effect of the Model on health care quality and Medicare spending. The evaluation will consider how the Model results may have been affected by any relevant changes in Medicare payment policy that became effective during the Model performance period.

An Evaluation Report will be publicly released for each performance year of the RO Model. Detailed methodologies and data sources used to create these estimates will be included in each Evaluation Report.

### **121. What is the process for CMS to take remedial action against an individual practitioner?**

CMS will monitor for compliance with model terms as well as other Medicare program rules. Under § 512.160, CMS may take remedial action against a model participant or a downstream participant, including an individual practitioner, if any of the grounds for remedial action exist (see 42 C.F.R. § 512.160(a)). In the case of remedial action based on the act or omission of an individual practitioner, we would typically notify the model participant and the individual practitioner of the grounds for remedial action and require the submission of additional information or a corrective action plan. Depending on the circumstances, CMS may also initiate action against RO participants or individual service providers under other existing authority, including 42 C.F.R. § 424.535(a).

## Resources

### 122. What resources are available to participants to guide them through the RO Model?

A variety of resources are available on the [RO Model website](#), including the following:

#### *Additional Information*

- Model Fact Sheet
- Participating ZIP Code List
- RO Beneficiary Letter
- RO Clinical Data Elements Informal Request for Information
- [PA Rural Health Model Eligible Hospitals](#)
- RO Model 101 Webinar and Webinar Slides
- ROAP User Manual (under the ROAP section of the RO Model website)

#### *Regulations and Notices*

- Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Final Rule (2020)

#### *Archived Materials*

- Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures Notice of proposed Rule Making (2019)
- RO Model Episode File (2015-2017)
- HCPCS\_CD Chemotherapy Codes File
- NDC Chemotherapy Codes File
- Major Procedures File
- RT Expenditures by Time
- Data Dictionary

#### *Educational Materials - Forthcoming*

- RO Included HCPCS Codes
- RO Trended National Base Rates
- RO Participant Billing Guide
- RO Participant Billing Guide Webinar
- Quality Measure and Clinical Data Element Collection Guide
- Case Mix and Historical Experience Adjustments Examples

### 123. How can I contact the team if I have additional questions?

The RO Model team can be reached at [RadiationTherapy@cms.hhs.gov](mailto:RadiationTherapy@cms.hhs.gov) or by calling the RO Model Help Desk at 1-844-711-2664, option 5.

### 124. Where can beneficiaries go with questions?

Beneficiaries can call 1-800-MEDICARE or contact their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs). Local BFCC-QIO contact information can be located here: <https://www.qioprogram.org/locate-your-qio>