hfma
healthcare financial management association

Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures
[CMS-5527-P]
Summary of Proposed Rule

On July 18, 2019, the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* a proposed rule that would implement two CMS Innovation Center models focused on providing specialty care to Medicare fee-for-service (FFS) beneficiaries with cancer and end-stage renal disease, respectively (84 FR 34478-34595). The proposed Radiation Oncology (RO) model would provide a bundled payment for an episode of radiation therapy to treat certain types of cancer. The proposed End-Stage Renal Disease Treatment Choices (ETC) model proposes payment adjustments intended to incent fully-informed beneficiary choices of renal replacement therapy options through adjustments to current payments to facilities and clinicians and by increasing flexibility in the delivery of the kidney disease education benefit. Participation in both models would be mandatory for eligible participants (facilities and clinicians) in selected geographic areas, and both models would commence in calendar year 2020.[1] **Comments on the proposed rule are due to CMS by September 16, 2019.**[2]

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[1] All references to years herein are to calendar years unless otherwise specified.

[2] CMS invites comments generally on all aspects of the proposed rule including the alternatives considered. More specific comment requests are highlighted in the relevant sections of this summary.

I. Overview

CMS proposes to implement two new mandatory specialty care models for Medicare FFS beneficiaries under the Innovation Center's authority to test innovative payment and service delivery models expected to reduce Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries (section 1115A of the Social Security Act (the Act)). CMS chose to focus the new models on radiation therapy (RT) and end-stage renal disease (ESRD) care, believing that significant opportunities exist in these two areas for redesigning care to be value-based and patient-centric while fostering alignment of financial incentives among providers.

A. Radiation Oncology Model (RO)

The proposed Radiation Oncology model builds upon the findings of the November 2017 report from the Secretary of Health and Human Services (HHS) to the Congress entitled *Episodic Alternative Payment Model for Radiation Therapy Services*.[3] Provision of this report was mandated by Section 3(b) of the Patient Access and Medicare Protection Act of 2015.[4] The RO model as proposed is an alternative payment model (APM) that provides a Medicare prospective, bundled-episode payment for clinician and facility services furnished during a course of RT delivered to treat certain cancer types. CMS identifies 17 cancer types that meet its model inclusion criteria including breast and prostate cancers. The payment would have professional

[3] https://innovation.cms.gov/files/reports/radiationtherapy-apm-rtc.pdf
[4] Public Law 114-115, enacted December 28, 2015

and technical components (PC and TC, respectively), include multiple services formerly billed separately (e.g., treatment planning and treatment delivery) and cover a 90-day episode of care. The RO model would transition to site-neutral payment on a common, adjusted national base payment amount for the episode, regardless of where it was furnished. This model would be mandatory in selected geographic areas and cover about 40 percent of RO episodes of care for Medicare beneficiaries. CMS states that the model would reduce provider burden by creating a simplified, predictable payment system for RT.

B. End-Stage Renal Disease Treatment Choices Model (ETC)

The proposed ESRD ETC model addresses the current pattern of patient distribution across renal replacement therapy options in the United States, a pattern that heavily favors in-center hemodialysis over home dialysis (hemodialysis or peritoneal dialysis (PD)), and that fails to transplant all viable donated kidneys.[5] This pattern is very costly,[6] and it differs substantially from those of other developed nations.[7] The ETC model is designed to test whether adjustments to existing payments to facilities and clinicians can increase rates of home dialysis and kidney transplantation. The ETC model is mandatory and would be implemented in randomly-selected Hospital Referral Regions (HRRs). Participants would be ESRD facilities and "Managing Clinicians"; the latter providers are those who bill Medicare's monthly capitated payment for directing care of beneficiaries with ESRD. Approximately one-half of facilities, managing clinicians, and ESRD beneficiaries nationally would be involved on the model test.

From 2020 through 2022, the ETC model would provide additional payment for claims submitted to Medicare by clinicians and facilities for home dialysis and related services through the Home Dialysis Payment Adjustment (HDPA). A separate Performance Payment Adjustment (PPA), based on home dialysis and transplantation rates, would apply to clinicians and facilities over the entire ETC model test period (final adjustments made June 30, 2026). The PPA could be either positive or negative depending upon clinician or facility performance.[8] To further progress towards the model's goal of fully informing beneficiary choices about their renal replacement therapy options, the ETC model would increase flexibility in the delivery of Medicare's kidney disease education (KDE) benefit by waiving certain KDE requirements. Taken together, these proposals are designed to substantially increase rates for home dialysis and kidney transplantation versus the use of in-center hemodialysis.

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[5] In this summary, kidney transplantation will be used to mean both kidney-only and kidney-pancreas transplantations, unless otherwise noted.

[6] In 2016, FFS Medicare expenditures for ESRD beneficiaries totaled $35.4 billion. See *Advancing American Kidney Health*, U.S. Department of Health and Human Services, released July 10, 2019. https://aspe.hhs.gov/system/files/aspe-files/262056/advancingamericankidneyhealth.pdf

[7] CMS Fact Sheet Proposed End-Sate Renal Disease Treatment Choices (ETC) Mandatory Model, released July 10, 2019. https://www.cms.gov/newsroom/fact-sheets/proposed-end-stage-renal-disease-treatment-choices-etc-mandatory-model

[8] The adjustments would be made through the Medicare Physician Fee Schedule for clinicians (i.e., to the monthly capitation payment for ESRD-beneficiary management) and through the ESRD Prospective Payment System (PPS) for facilities (i.e., to per treatment adjusted base rate for facilities).

CMS estimates that the combined financial impact of the proposed RO Model and the ETC Model would be a net federal savings of $429 million over a 5-year performance period (2020 through 2024). Of this net federal savings, $169 million is estimated to come from the RO Model and $260 million from the ETC Model. CMS anticipates a negligible impact on the cost of beneficiaries receiving RT services and on the cost of receiving dialysis. CMS believes that the beneficiary's quality of life has the potential to improve under both models based on an incentive to use fewer RT services, when medically appropriate, and the expansion of home dialysis as opposed to in-center dialysis.

Some key features of the RO and ETC models are shown in the table below.

KEY FEATURES OF PROPOSED SPECIALTY CARE MODELS			
	RADIATION ONCOLOGY (RO)	**ESRD TREATMENT CHOICES (ETC)**	**Notes**
Model start date	January 1, 2020	January 1, 2020	
Model end date	December 31, 2024 (last date during which episodes under the model must be completed)	June 30, 2026	
Model category	Episode-based payment initiative	Initiative for adoption best practices	a
Model participation	Mandatory if selected (geographic areas published once final rule is displayed)	Mandatory if selected	
Geographic unit of selection	Core-based statistical area (CBSA)	Hospital Referral Region (HRR)	
Participants - Clinicians	Radiation oncologists	ESRD Managing Clinician (e.g., nephrologist)	b
Participants - Facilities	Medicare enrolled Physician Group Practice (PGP), Freestanding RT center and HOPD	Dialysis facilities (in-center and home)	c
Participant Exclusions	Excludes PGPs, Freestanding RT Centers and HOPDs in Maryland, Vermont, or U.S. Territories	Clinicians and Facilities in US Territories	
Beneficiary eligibility	Fee-for-service, selected common cancer diagnoses – 17 cancer types (e.g., breast, prostate). Other exclusions include enrollment in a MA or PACE plan, among others.	Fee-for-service beneficiaries age 18 or older with ESRD	d
Beneficiary attribution/alignment	Includes beneficiaries that receive included RT services in a selected CBSA from a RO participant for a cancer type included in model. At initial treatment planning, beneficiary (1) is eligible for Medicare Part A and enrolled in Medicare Part B; and (2) Medicare FFS as his or her primary payer.	Monthly; claims-based; to managing clinician and to dialysis facility	
Episode Definition	90-day episode covering treatment planning services and radiation therapy services. Excludes E&M services. Triggered by a treatment planning code and a RT service within 28 days. New episode cannot begin until 28 days after end of initial episode – “clean period”.	Not an episode model	

Minimum patient volume	Excludes low-volume RT services	Low-volume exclusions (clinician and facility) for Performance Payment Adjustment (PPA)	
Payment change methodology	Prospective 90-day bundled site-neutral payment replaces billing of multiple services during RT episode (e.g., technical episode payment same in freestanding RT centers and HOPDs). Thirty-four national rates (17 for technical episodes and 17 for professional episode) adjusted for RO-participant's case mix, historical experience and efficiency, and geographic location. Payments are also adjusted for withholds: incomplete episodes, quality, and beneficiary experience in PY3. Payment is made in two installments	Two adjustments are applied to existing payments to managing clinicians (monthly capitation payment paid under PFS) and facilities (ESRD PPS per treatment base rate) to encourage home dialysis and transplantation; Home Dialysis Payment Adjustment (HDPA) and Performance Payment Adjustment (PPA).	
Provider Payment risk	Two-sided, applies a uniform discount factor of 4 percent for PC episode payments and 5 percent for TC episode payments. This is savings built into model for Medicare.	Two-sided for Performance Payment Adjustment (The HDPA is a uniformly positive payment adjustment.)	
Quality-linked payment	Yes	No	e
Payment waivers applicable	Yes, Key waivers: Waives application of MIPS payment adjustment factors for PC payments; and waives inclusion of TC payments in calculation of the APM Incentive Payment amount. Applies to RO Model-specific HCPCS codes	Yes (to permit the proposed payment adjustments)	f
Beneficiary Cost Sharing	Twenty percent cost-sharing for each of the bundled PC and TC payments	Twenty percent cost-sharing	
Benefit enhancement	Negligible impact on the cost to beneficiaries. Incentivizes treatment plan that requires fewer services, when medically appropriate.	Increased flexibility KDE benefit, improves beneficiary choice of ESRD treatment options.	g
Advanced APM/MIPS APM	Yes/Yes	No/No	h

a CMS Innovation Center model categories; the category to which the ETC model is assigned has been inferred from the proposed rule
b ESRD = end-stage renal disease; Managing clinician = a Medicare-enrolled physician or non-physician practitioner who manages an adult ESRD beneficiary and bills the monthly capitation payment
c RT = radiation therapy; HOPD = Hospital Outpatient Department
d MA = Medicare Advantage: PACE = Programs of All-Inclusive Care for the Elderly
e Independent of the ETC model, clinician payment is subject to the Quality Payment Program (QPP) and facility payment is subject to the ESRD Quality Improvement Program (ESRD QIP)
f HCPCS = Healthcare Common Procedure Coding System
g KDE = kidney disease education benefit; eligible beneficiary and practitioner pools expanded under ETC model
h APM = Alternative Payment Model; MIPS = Merit-based Incentive Payment System (part of the QPP)

II. General Provisions Applicable to the RO and ETC models

A. Overview

CMS proposes to amend 42 CFR chapter 4 by adding implementing regulations for the RO and ETC models in new part 512. Subpart A would contain provisions applicable to both models, while the provisions of subparts B and C would apply, respectively, to either the RO or ETC model. The regulations proposed in subpart A are analogous to many already implemented in other Innovation Center models dealing with beneficiary protections, model evaluation, compliance with model requirements and applicable laws, and monitoring. Unless specifically noted, subpart A regulations as proposed would not affect the applicability of existing Medicare FFS provisions for providers and suppliers dealing with payment, coverage, and program integrity (e.g., 42 CFR Chapter IV parts 413 and 420). The effective date for the proposed subpart A regulations is not stated but likely would be on or before January 1, 2020, the stated start date for the proposed payment adjustments under the ETC model.

CMS defines several terms at §512.100, including the following:

- *Model beneficiary*: a beneficiary enrolled in Medicare FFS and attributed to a model participant or otherwise included in the RO or ETC models.
- *Downstream participant:* an individual or entity that has entered into a written arrangement with a model participant pursuant to which the downstream participant engages in one or more Innovation Center model activities.
- *Innovation Center model activities*: any activities impacting the care of model beneficiaries related to the test of the Innovation Center model.
- *Model-specific payment:* a payment by CMS only to model participants, or a payment adjustment only to payments made to model participants, under the terms of the Innovation Center model that is not applicable to any other providers or suppliers.

Additional terms are defined when specifically discussed in other sections of the rule.

B. Beneficiary Protections

1. Freedom of Choice (§512.120(a))

To ensure that RO and ETC model testing as proposed does not undermine FFS beneficiary freedom of choice, CMS proposes the following:

- Model and downstream participants may not restrict beneficiaries' abilities to choose their providers or suppliers.
- Model and downstream participants may not inhibit beneficiaries from choosing to receive care from any Medicare-participating provider or supplier, or from any health care provider who has opted out of Medicare.

    - Model and downstream participants may communicate to beneficiaries the benefits of care furnished by the model participants.
- The terms *provider* and *supplier* would be used as currently codified at 42 CFR 400.202.

2. Availability of Service (§512.120(b))

To ensure that beneficiaries included in the RO and ETC models have continued access to and receive needed care, CMS proposes the following:

- Model and downstream participants must continue to make medically necessary covered services available to beneficiaries.
- The terms *medically necessary* and *covered services* would be used, respectively, in a manner consistent with section 1862(A)(1)(a) or sections 1812 and 1832 of the Act.
- Model beneficiaries and their assignees would retain their rights to appeal claims in accordance with 42 CFR part 405, subpart I.
- Model and downstream participants would be prohibited from avoiding treatment of at-risk beneficiaries as defined at §425.20 (e.g., "lemon dropping").[9]
- Model and downstream participants would be prohibited from selectively engaging beneficiaries who are relatively healthy or otherwise expected to improve the financial or quality performances of model and/or downstream participants ("cherry picking").

CMS seeks comment on whether prohibiting cherry picking will prevent model participants from artificially inflating their financial or quality performance results.

3. Descriptive Model Materials and Activities (§512.120(c))

CMS states that payments to a model's participants could incent marketing behavior that would confuse or mislead beneficiaries. To reduce the risks of such behavior, CMS proposes that:

- The term *descriptive model materials and activities* would be applied to general audience materials or other materials or activities that are 1) distributed or conducted by or on behalf of RO or ETC model or downstream participants, and 2) used to educate, notify, or contact beneficiaries regarding the models.
    - General audience materials could include brochures, advertisements, outreach events, letters, web pages, mailings, and social media postings.
- Communications that would not be considered descriptive model materials and activities are those that 1) do not directly or indirectly reference the model (e.g., general discussion of care coordination); 2) do address specific medical conditions; 3) do make referrals for needed items and services; or 4) are excepted from "marketing" at 45 CFR 164.501.
- All descriptive model materials and activities must include a standardized disclaimer.
    - *"The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of the Centers for Medicare and*

[9] At risk beneficiaries include those with one or more chronic conditions or who are entitled to Medicaid because of disability, along with other markers of potentially increased costs. This definition was developed for use in the Medicare Shared Savings Program.

Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document."

- Model and downstream participants would be prohibited from using or distributing descriptive model materials and activities that are materially inaccurate or misleading.[10]
- CMS reserves the right to review descriptive model materials and activities to determine whether the content is materially inaccurate or misleading.
    - CMS would specify the time and manner of the review once such descriptive model materials and activities are in use by the model participant.
- Model and downstream participants must retain copies of all written and electronic descriptive model materials and activities and appropriate records for all other descriptive model materials and activities in a manner consistent with §512.135(c).

CMS seeks comment on whether the disclaimer should be modified to alert beneficiaries to the prohibition against distributing misleading information and to inform them how to contact CMS after receiving RO or ETC model information that they suspect is inaccurate.

C. Model Evaluation, Monitoring and Compliance

1. Model Evaluation (Section 1115A of the Act, §403.1110(b), §512.130)

Models tested under Innovation Center authority (section 1115A of the Act) must be evaluated, and the analysis must include quality of care and program spending changes. The evaluation results must be reported publicly and in a timely manner. Entities participating in model testing must comply with regulations at §403.1110(b) to collect and report information that the Secretary determines necessary to evaluate the models. Required data may include protected health information and must be produced per the Secretary's specifications. CMS proposes at §512.130 that RO and ETC model and downstream participants must provide the requested information and otherwise cooperate with model evaluation activities (e.g., surveys, focus groups). CMS further proposes at §512.130 that those participants must comply and cooperate with other model monitoring activities as outlined at §512.150.

2. Monitoring and Compliance (§512.150)

CMS routinely monitors Innovation Center model participants for compliance with the terms of their respective models, and all other applicable laws and regulations (absent specific model waivers). For the RO and ETC models, CMS proposes that monitoring activities with which RO and ETC model and downstream participants must comply may include 1) documentation requests (e.g., surveys and questionnaires); 2) audits of claims, quality measures, medical records, and other types of data; 3) interviews with participant leaders and staff members; 4) interviews with beneficiaries and their caregivers; 5) site visits; 6) monitoring of quality outcomes and clinical data; and 7) tracking patient complaints and appeals. When conducting

[10] CMS notes that the proposed prohibition "in no way restricts the ability of a model or downstream participant to engage in activism or otherwise alert model beneficiaries to the drawbacks of mandatory models in which they would otherwise decline to participate, provided that such statements are not materially inaccurate or misleading".

monitoring activities, CMS or its designee would be authorized to use any relevant data or information including Medicare claims involving model beneficiaries.

Regarding site visits conducted by CMS or its designee, CMS proposes that model and downstream participants must cooperate in the visits and ensure that appropriately knowledgeable and responsible personnel are available. CMS proposes to provide participants with notice of any site visit at least 15 days in advance and to accommodate scheduling requests, whenever feasible.[11] CMS proposes to perform unannounced site visits at any time to model and downstream participants to investigate patient health and safety concerns or program integrity issues.

CMS further proposes having a "right to correct". Upon discovering having made or received an incorrect model-specific payment, CMS subsequently may make payment to, or demand payment from, the model participant(s) involved. Finally, CMS proposes that nothing in the terms of the proposed RO and ETC models, nor elsewhere in proposed part 512, would limit or restrict the investigative functions of the HHS Office of the Inspector General (OIG) or any other Federal Government authority when directed towards potential violations of statutes, rules, or regulations by model or downstream participants.

CMS seeks comment on whether CMS should be able to reopen an initial determination of a model-specific payment for any reason within 1 year of the model-specific payment, and within 4 years for good cause (as defined at 42 CFR 405.986). This provision would provide a timeline and mechanism for making redeterminations of incorrect model-specific payments consistent with the "right to correct" described above.

D. Audits and Record Retention (§512.135)

1. Right to Audit

CMS notes that audit and record retention requirements currently apply to several Innovation Center models (e.g., Comprehensive Care for Joint Replacement). Audits of model participants aid CMS in assuring that beneficiary access to medically necessary items and services is not being constrained by participants and in detecting irregularities related to model-specific payments, payment waivers, or other model-specific flexibility provisions. CMS notes that the RO model's "participant-specific professional episode payment" and "participant-specific technical episode payment", as well as the ETC model's payment adjustments (HDPA and PPA) are considered model-specific payments. Therefore, CMS proposes that the Federal Government -- including CMS, HHS, and the Comptroller General, or their designees -- has the right to audit, inspect, investigate, and evaluate any documents and other evidence related to implementation of the RO and ETC models.

[11] Site visit dates falling more than 60 days after the date of the initial site visit notice may not be requested by participants.

2. Record Access

CMS proposes that RO and ETC model and downstream participants must maintain and give the Federal Government -- including CMS, HHS, and the Comptroller General, or their designees – access to all documents and other evidence sufficient to enable the audit, evaluation, inspection, or investigation of any model implementation question or concern. Included without limitation is access to materials dealing with the following:

- Compliance by model and downstream participants with the terms of their respective models;
- Model-specific payment accuracy;
- Model-specific repayment amounts owed to CMS;
- Quality measure information and the quality of services performed under the model;
- Utilization of items and services furnished under the model;
- Model participant ability to bear risk for potential losses and to repay losses to CMS;
- Patient safety; and
- Other program integrity issues.

3. Record Retention

CMS proposes that model and downstream participants must maintain all required documents and evidence for a 6-year period following the last model-specific payment determination or the completion date of any audit, evaluation, inspection, or investigation, whichever is later. CMS would retain the option to determine that a special need exists to retain a particular record or group of records for a longer period. CMS would be required to notify the participant of the special need at least 30 days before the normal retained record disposition date. When there has been a termination, dispute, or allegation of fraud or similar fault against a model or downstream participant, records must be maintained for an additional six years from the date of any resulting final resolution of the termination, dispute, or allegation of fraud or similar fault. In the case of a special record retention need or the occurrence of a termination, dispute, or allegation of fraud or similar fault involving a model or downstream participant, the model participant would be required to notify its downstream participants of the extended record retention period.

E. Remedial Action (§512.160)

1. Grounds for Imposing Remedial Action

CMS proposes the following as grounds for imposing remedial action(s) on a model or downstream participant after determining that the participant:

(i) Has failed to comply with any of the terms of the applicable model;
(ii) Has failed to comply with any applicable Medicare program requirement, rule, or regulation;
(iii) Has taken any action that threatens the health or safety of a beneficiary or other patient;

(iv) Has submitted false data or made false representations, warranties, or certifications in connection with any aspect of the applicable model;
(v) Has undergone a change in control that presents a program integrity risk;
(vi) Is subject to any sanctions of an accrediting organization or a Federal, state, or local government agency;
(vii) Is subject to investigation or action by HHS (including the OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint or filing of a criminal charge, being subject to an indictment, being named as a defendant in a False Claims Act *qui tam* matter in which the Federal Government has intervened, or similar action; or
(viii) Has failed to demonstrate improved performance following any remedial action imposed under section 512.

2. Potential Remedial Actions

After finding that that one or more grounds for imposing remedial action on a model or downstream participant has occurred, CMS proposes to select remedial action(s) from the list below.

- Notify the model participant and, if appropriate, require the model participant to notify its downstream participants of the violation;
- Require the participant to provide additional information to CMS or its designee;
- Subject the participant to additional monitoring, auditing, or both;
- Prohibit the participant from distributing model-specific payments, as applicable;
- Require the model participant to terminate, immediately or by a deadline specified by CMS, its agreement with a downstream participant with respect to the model;
- Require the participant to submit a corrective action plan in a form and manner and by a deadline specified by CMS;
- Discontinue the provision of data sharing and reports to the model participant;
- Recoup model-specific payments;
- Reduce or eliminate a model-specific payment otherwise owed to the model participant;
- Such other action as may be permitted under the terms of part 512; or
- In the ETC Model only, terminate the ETC Participant from the ETC Model.

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CMS seeks comment whether additional types of remedial action would be appropriate.

F. Limitations on Review (§512.170)

CMS proposes that there is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for all of the following:

1) Selection of models for testing or expansion under section 1115A of the Act;
2) Selection of organizations, sites, or participants, including model participants, to test the models selected, including a decision by CMS to remove a model participant or to require a model participant to remove a downstream participant from the model;

3) Elements, parameters, scope, and duration of models for testing or dissemination;
    a. Selection of quality performance standards for the Innovation Center model by CMS.
    b. Assessment by CMS of the quality of care furnished by the model participant.
    c. Attribution of model beneficiaries to the model participant by CMS, if applicable.
4) Determinations regarding budget neutrality under section 1115A(b)(3) of the Act;
5) Termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act; and
6) Determinations about expansion of the duration and scope of a model under section 1115A(c) of the Act, including the determination that a model is not expected to meet criteria described in paragraph (a) or (b) of such section.

G. Other Provisions

1. Data and Intellectual Property Rights (§512.140)

CMS proposes that any data obtained in accordance with §§512.130, 512.135, and 512.150 may be used to evaluate and monitor the RO and ETC models. CMS also proposes that qualitative and quantitative results, successful care management techniques, and performance-associated factors may be disseminated to other providers and supplies and to the public. CMS further proposes that the disseminated data may include de-identified results calculated based upon claims, medical records, and other data sources, as well as on de-identified survey results about patient experience of care and quality of life.

CMS additionally proposes that model or downstream participants may request that CMS protect proprietary or confidential information submitted to CMS. The material to be protected must be labeled or identifiable as proprietary or confidential and CMS proposes to review and confirm the material to be proprietary or confidential before acting based upon those labels. CMS proposes not to release confirmed proprietary or confidential information without the expressed consent of the model or downstream participant, unless release is required by law.

2. Model Termination by CMS (§512.165)

Reasons proposed for CMS to terminate the RO and/or ETC models would include but not be limited to lack of CMS funding sufficient to support the model, or failure to meet criteria for expansion of the duration and scope of a model under section 1115A(c) of the Act.[12] CMS proposes to provide written notice of model termination to model participants, including the effective date of and grounds for termination.

[12] Expansion is based upon increasing quality of care while decreasing or holding neutral program expenditures or upon decreasing expenditures without reducing quality of care. Model termination for failing to meet model expansion criteria is not subject to administrative or judicial review.

3. Bankruptcy and Related Notifications (§512.180)

CMS proposes that model participants notify CMS of events that could impact their ability to meet their financial obligations under the model, including payment of monies owed to CMS. First, CMS proposes that a participant that files a voluntary or involuntary bankruptcy petition must provide written notice of the bankruptcy to CMS and to the local U.S. Attorney's Office by certified mail within 5 days of filing the bankruptcy petition.[13] **CMS seeks comment on whether to require that the bankruptcy notice be sent to the applicable CMS regional office in addition to or in lieu of being sent to CMS headquarters in Baltimore.**

Second, CMS proposes that a model participant must provide written notice to CMS at least 60 days before the effective date of any change in the participant's legal name. **CMS seeks comment on whether the typical name change procedure would allow for 60-days advance notice to CMS and on the alternative of requiring notice to be provided within 30 days after the effective date of a legal name change.**

Third, CMS proposes that a model participant must provide written notice to CMS at least 90 days before the effective date of any change in control. CMS proposes to define *change in control* as any of the following:

- Acquisition by any "person" of beneficial ownership, directly or indirectly, of voting securities of the model participant representing more than 50 percent of the model participant's outstanding voting securities or rights to acquire such securities;[14]
- Acquisition of the model participant by any individual or entity;
- Sale, lease, exchange or other transfer (in one transaction or a series of transactions) of all or substantially all of the assets of the model participant; or
- Approval and completion of a liquidation plan of the model participant, or an agreement for the sale or liquidation of the model participant.

Fourth, CMS proposes that immediate reconciliation and payment of all monies owed to CMS may be required of a model participant that is subject to a change in control. CMS further proposes that remedial action could be taken against a model participant whose change in control is determined by CMS to present a Medicare program integrity risk.

[13] Providing notice would not be required only if final payment has been made by either CMS or the model participant under the terms of each section 1115A model in which the now-bankrupt participant is participating or has participated and all administrative or judicial review proceedings relating to any payments under such models have been fully and finally resolved.

[14] "Person" would mean as such term is used in sections 13(d) and 14(d) of the Securities Exchange Act of 1934; "beneficial ownership" would mean as such term is used within the meaning of Rule 13d-3 promulgated under the Securities Exchange Act of 1934.

III. Radiation Oncology Model

A. Introduction

CMS proposes a mandatory Radiation Oncology Model (RO Model) to test whether prospective episode-based payments for radiotherapy or radiation therapy (RT) services would reduce Medicare program expenditures and preserve or enhance quality of care. This model would be mandatory in selected geographic areas. Under this proposed model, Medicare would pay participating providers and suppliers a site-neutral, episode-based payment for specified professional and technical RT services furnished during a 90-day episode to Medicare fee-for-service (FFS) beneficiaries diagnosed with certain cancer types. Base payment amounts would be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. The performance period would be for five performance years (PYs) beginning in 2020.

The following proposals for the RO Model are discussed in the proposed rule:

- Scope of the model, including required participants and episodes under the model test;
- Pricing methodology under the model and necessary Medicare program policy waivers to implement such methodology; quality measures selected for the model for purposes of scoring a participant's quality performance; process for payment reconciliation; and, data collection and sharing.

B. Background

In this section of the proposed rule, CMS provides background information on the use of radiation oncology, the latest research, coding and payment challenges.

As background, RT is a common treatment for nearly two thirds of all patients undergoing cancer treatment[15, 16] and is typically furnished by a radiation oncologist. CMS analyzed Medicare FFS claims between January 1, 2015 and December 31, 2017, to examine radiation services furnished to Medicare beneficiaries during that period. CMS specifically examined HOPD and Medicare Physician Fee Schedule (PFS) claims to identify all FFS beneficiaries who received any radiation treatment delivery services within that 3-year period. Its analysis shows that HOPDs furnished 64 percent of episodes nationally, while freestanding radiation therapy centers furnished the remaining 36 percent of episodes.[17] CMS notes that episodes provided at freestanding radiation therapy centers were, on average, paid approximately $1,800 (or 11 percent) more by Medicare than those episodes of care where RT was furnished at a HOPD. CMS states that it doesn't appear that a clinical rationale explains the difference in resource costs, although it observes that freestanding radiation therapy centers use more IMRT, which is associated with higher Medicare payments.

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[15] Physician Characteristics and Distribution in the U.5., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.

[16] Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).

[17] CMS states that it intends to make this data publicly accessible in a summary-level, de-identified file titled "RO Episode File (2015-2017)," on its website: https://innovation.cms.gov/initiatives/radiation-oncology-model/

CMS notes that RT services are paid differently based on the site-of-service. Under Medicare FFS, RT services furnished in a freestanding radiation therapy center are paid under the Medicare PFS at the non-facility rate including payment for the professional and technical aspects of the services. For RT services furnished in an outpatient department of a hospital, the facility services are paid under the Hospital Outpatient Prospective Payment System (OPPS) and the professional services are paid under the PFS. CMS notes that such payment differentials may provide an incentive to Medicare providers and suppliers to deliver RT services in one setting over another. Its RO Model plans to test a site-neutral payment rather than implementing a payment adjustment in the OPPS or PFS, which would require additional statutory authority and doesn't allow flexibility to test new value-based payment approaches.

CMS cites research that for some cancer types, stages, and characteristics, a shorter course of RT treatment with more radiation per fraction may be appropriate. CMS is concerned that the current Medicare FFS payment system may incentivize selection of a treatment plan with high volume of services over a more medically appropriate treatment plan that requires fewer services.

Through its annual Medicare PFS rulemaking process, CMS states that it has reviewed and finalized payment rates for several RT codes over the past few years, but there have been challenges related to information used to establish payment rates for RT services. Statutory changes have also addressed payment for certain RT delivery, and related imaging services under the PFS. The Patient Access and Medicare Protection Act (PAMPA) (Pub. L. 114-115), enacted on December 28, 2015, and the Bipartisan Budget Act (BBA) of 2018 (Pub.L. 115-123) required the PFS to use the same service inputs for these codes as existed in 2016 for CY 2017, 2018, and 2019. PAMPA also required the Secretary to submit a Report to Congress on development of an episodic alternative payment model (APM) for Medicare payment for radiation therapy services furnished in non-facility settings. CMS states that although the report discussed several options for an APM, it proposes what the Innovation Center has determined to be the best design for testing an episodic APM for RT services.

C. RO Model Proposed Regulations

CMS proposes to codify RO Model policies at 42 CFR part 512, subpart B (proposed §§512.200 through 512.290). Definitions of certain terms for the RO model are proposed at §512.205. The general provisions proposed to be codified at §§512.100 through 512.180 would apply to the proposed RO Model.

1. Proposed Model Performance Period

CMS proposes to test the RO Model for 5 performance years (PYs). A PY, as proposed, would be a 12-month period beginning on January 1 and ending on December 31 of each year during the model performance period (§512.205). The "model performance period" would be defined as January 1, 2020 through December 31, 2024 (the last date during which episodes under the model must be completed). CMS also discussed an alternative that would delay implementation to April 1, 2020 to give RO participants and CMS more time to prepare. This would only affect the length of PY1, which would be 9 months.

CMS invites comments on the proposed model performance period and potential participants' ability to be ready to implement the RO Model by January 1, 2020. It also seeks comments on delaying the start of the model performance period to April 1, 2020.

2. Proposed Definitions

CMS proposes at §512.205 to define certain terms of the RO Model. These proposed definitions are described through section III of the proposed rule. **CMS invites comment on these proposed definitions.**

3. Proposed Participants

In this section, CMS describes its proposal regarding mandatory participation, the types of entities that would be required to participate, and the geographic areas that would be subject to the RO Model test.

a. Proposed Required Participation

CMS proposes that participation in this RO model would be mandatory for the RT providers and suppliers that furnish RT services within randomly selected Core-Based Statistical Areas (CBSAs). The geographic unit of selection is discussed below. CMS notes that the Innovation Center has only tested one voluntary prospective episode payment model, the Bundled Payments for Care Improvement (BPCI) Model 4 that attracted only 23 participants, of which almost four-fifths withdrew from the initiative. It concludes that few to no HOPDs would elect to voluntarily participate in the model, as OPPS rates are expected to increase substantially more than PFS rates from 2019 through 2023. CMS believes a broad representative sample of RT providers and suppliers for the proposed model is necessary to develop a robust data set for evaluation of this prospective payment approach.

Thus, CMS proposes that participation in the RO model would be mandatory for all RT providers and RT suppliers furnishing RT services within the randomly selected CBSAs.

CMS invites comments on its proposal for mandatory participation.

b. Proposed RO Model Participants

CMS proposes definitions for a "RO participant" and participation in the model as a "Professional Participant", "Technical Participant", "Dual participant", and "individual practitioner". These proposed definitions are summarized in the table below and defined at §512.205 in the proposed regulations.

Term	Proposed Definition
RO participant	Medicare-enrolled physician group practices (PGP), freestanding radiation therapy center, or HOPD that participates in the RO Model pursuant to §512.210. A RO participant may be a Dual participant, Professional participant, or Technical participant.
Professional participant	RO participant that is a Medicare-enrolled PGP identified by a single Taxpayer Identification Number (TIN) that furnishes only the professional component (PC) of an episode.
Technical participant	RO participant that is a Medicare-enrolled HOPD or freestanding radiation therapy center, identified by a single CMS Certification Number (CCN) or TIN, which furnishes only the technical component (TC) of an episode.
Dual participant	RO participant that furnishes both the PC and TC of RT services of an episode through a freestanding radiation therapy center, identified by a single TIN.
Individual practitioner	Medicare-enrolled physician (identified by an NPI) who furnishes RT services to Medicare FFS beneficiaries, and has reassigned their billing rights to the TIN of a RO participant.

CMS notes that professional participants would be required to annually attest to the accuracy of an individual practitioner list (provided by CMS), of all of the eligible clinicians who furnish care under the Professional participant's TIN.

A RO participant would furnish at least one component of an episode: a "professional component" (PC) or a "technical component" (TC). The proposed definition of a PC is the included RT services that may only be furnished by a physician. The proposed definition of a TC is the included RT services that are not furnished by a physician, including the provision of equipment, supplies, personnel, and costs related to RT services. Thus, an episode of RT under this model would be furnished by either (1) two separate RO participants – a Professional participant that furnishes only the PC of an episode, and a Technical participant that furnishes only the TC of an episode; or (2) a Dual participant that furnishes both PC and TC of an episode. For instance, a PGP could furnish only the PC of an episode at a HOPD that furnishes the TC of the episode.

c. Proposed RO Model Participant Exclusions

CMS proposes to exclude from RO Model participation any PGP, freestanding radiation therapy center, or HOPD that furnishes RT only in Maryland, Vermont, and in U.S. Territories. Both Maryland and Vermont have unique statewide payment models that would interfere with their payment systems and the evaluation of the RO Model. CMS also proposes to exclude any PGP, freestanding radiation therapy center or HOPD that is classified as an ambulatory surgery center (ASC), critical access hospital (CAH), or Prospective Payment System (PPS)-exempt cancer hospital; or participates in or is identified as eligible to participate in the Pennsylvania Rural Health Model. These exclusion criteria would apply during the entire model performance period.

A change in the location of the RO participant or change in its classification could affect whether the participant would be excluded from the model. If a RO participant moves its location from one of the randomly selected CBSAs to a location where the exclusion criteria apply, then it

would be excluded from the RO Model from the date of its location change. The converse would also be true. Likewise, if an HOPD, for example, was no longer classified as a PPS-exempt hospital and the HOPD was located in one of the randomly selected CBSAs, then the HOPD would become an RO participant from the date that the HOPD became no longer classified as a PPS-exempt hospital.

CMS clarifies in the case of Professional participants and Dual participants, any episodes in which the initial RT treatment planning service is furnished to a RO beneficiary on or after the day of this change would be included in the model. In the case of Technical participants, any episodes where the RT service is furnished within 28 days of a RT treatment planning service for a RO beneficiary and the RT service is furnished on or after the day of this change would be included in the model

CMS proposes to codify these policies at §512.210 of its regulations. **CMS invites comments on these proposals.**

d. Proposed Geographic Unit of Selection

CMS proposes that the geographic unit of selection for the RO Model would be OMB's 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 (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).[18] CMS states that it chose CBSAs as the proposed geographic unit of selection as they are ideal for use in statistical analyses because there are of sufficient number to allow for robust analysis and large enough to reduce the number of RO participants in close proximity to other RT providers and suppliers that would not be required to participate in the model.

CMS proposes to use an RT provider's or RT supplier's service location five-digit ZIP Code found on the RT provider's or RT supplier's claim submissions to CMS to link them to CBSAs selected under the model. CMS notes, however, that 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 – about 15 percent of five-digit ZIP Codes have portions of their addresses located in more than one CBSA. If each ZIP Code was assigned only to the CBSA with the largest portion of delivery locations in it, about 5 percent of all delivery locations in ZIP Codes would be assigned to a different CBSA.

CMS proposes to assign 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. CMS states that in the case where the portion of total addresses within the five-digit ZIP Code is equal across CBSAs, it would use the greater portion of business addresses to link a ZIP Code to the CBSA.

[18] CBSAs are defined by the Office of Management and Budget and published on Census.gov

CMS believes that this approach would decrease provider burden, as RT provider and suppliers would not need to provide more detailed geographic data.

CMS would use a five-digit ZIP Code to CBSA crosswalk found in the Housing and Urban Development (HUD) ZIP to CBSA Crosswalk file[19] to link each five-digit ZIP Code to a single CBSA. If finalized, CMS states that it would provide a look-up tool on the RO Model website that includes all five-digit ZIP Codes linked to CBSAs.

To select CBSAs under the model, CMS proposes to use a stratified sample design based on the observed ranges of episode counts in CBSAs using claims data calendar years 2015-2017. The strata would be divided into five quintiles based on the total number of episodes within a given CBSA. CMS states that it would then randomize the CBSAs within each stratum into participant and comparison groups until the targeted number of RO episodes within each group of CBSAs needed for a robust test of the model is reached. CMS goes on to say that it plans to sample 40 percent of all eligible RO episodes in eligible CBSAs nationwide and it should be "powered" sufficiently to show the impact of the model.

CMS does not list the proposed CBSAs that would be chosen based on this approach in the proposed rule. It states that the CBSAs would be randomly selected and those CBSAs and the ZIP codes selected for participation would be published on the RO Model website once the final rule is displayed.

4. Proposed Beneficiary Population

CMS proposes that a Medicare FFS beneficiary be <u>included</u> in the RO Model if the beneficiary:

- Receives included RT services in a five-digit ZIP Code linked to a selected CBSA from a RO participant during the model performance period for a cancer type that meets the criteria for inclusion in the RO Model; and
- At the time that the initial treatment planning service of the episode is furnished by a RO participant, the beneficiary (1) is eligible for Medicare Part A and enrolled in Medicare Part B; and (2) has traditional Medicare FFS as his or her primary payer.

In addition, CMS proposes to <u>exclude</u> from the RO Model any beneficiary who, at the time that the initial treatment planning service of the episode is furnished by a RO participant:

- Is enrolled in any Medicare managed care organization, including but not limited to Medicare Advantage plans;
- Is enrolled in a PACE plan;
- Is not in a Medicare hospice benefit period; or
- Is covered under United Mine Workers.

CMS proposes these criteria in order to limit RT provider and RT supplier participation in the RO Model to beneficiaries whose RT providers and RT suppliers would otherwise be paid by way of traditional FFS payments for the identified cancer types. Under this proposal, a

[19] Datasets and documentation for HUD USPS Zip Code Crosswalk Files can be found here: https://www.huduser.gov/portal/datasets/usps_crosswalk.html

beneficiary who meets all of these criteria, and who does not trigger any of the beneficiary exclusion criteria, would be called a "RO beneficiary". CMS proposes to codify the terms "RO beneficiary," "RT provider," and "RT supplier" at §512.205.

In addition, CMS proposes to include in the RO Model any beneficiary participating in a clinical trial for RT services for which Medicare pays routine costs, provided that such beneficiary meets all of the proposed beneficiary inclusion criteria.

The RO Model's proposed design would not allow RO beneficiaries to "opt out" of the Model's pricing methodology. A beneficiary who is included in the RO Model pursuant to the previously proposed criteria would have his or her RT services paid for under the model's pricing methodology and would be responsible for the coinsurance amount.

5. Proposed RO Model Episodes

Under the proposed RO Model, Medicare would pay RO participants a site-neutral, episode-based payment amount for all specified RT services furnished to a RO beneficiary during a 90-day episode. This section discusses CMS proposal to add or remove cancer types, including the relevant diagnosis codes, as well as the RT services and modalities that would be covered and not covered in an episode payment. In addition, this section describes CMS' proposal for the conditions that must be met to trigger a 90-day episode.

a. Proposed Included Cancer Types

CMS proposes the following criteria for including cancer types under the RO Model. The cancer type is

- commonly treated with radiation; and
- has associated current ICD-10 codes that have demonstrated pricing stability.

Its proposed criteria for removing cancer types under the RO Model are the following:

- RT is no longer appropriate to treat a cancer type per nationally recognized, evidence-based clinical treatment guidelines;
- CMS discovers a ≥10 percent (≥10%) error in established national baseline rates; or
- The Secretary determines a cancer type not to be suitable for inclusion in the Model.

CMS proposes to codify these requirements at §512.230(a) and §512.230(b) of its regulation.

CMS identified 17 cancer types in Table 1 (reproduced below) that meet its proposed criteria. CMS states that these 17 cancer types are commonly treated with RT and Medicare claims data was sufficiently reliable to calculate prices for prospective episode payments that accurately reflect the average resource utilization for an episode. These cancer types include, for example, "breast cancer", which is a categorical grouping of ICD-9 and ICD-10 codes affiliated with this condition. Based on its analyses, CMS excluded benign neoplasms and those cancers that are rarely treated with radiation, as there were not enough episodes for reliable pricing and the variation among them was too much to pool them into a category. CMS also excluded skin

cancers due to the variability in the coding for these services and changes to local coverage determination during its data analysis period.

Table 1: Identified Cancer Types and Corresponding ICD-9 and ICD-10 Codes

Cancer Type	ICD-9 Codes	ICD-10 Codes
Anal Cancer	154.2x, 154.3x	C21.xx
Bladder Cancer	188.xx	C67.xx
Bone Metastases	198.5x	C79.5x
Brain Metastases	198.3x	C79.3x
Breast Cancer	174.xx, 175.xx, 233.0x	C50.xx, D05.xx
Cervical Cancer	180.xx	C53.xx
CNS Tumors	191.xx, 192.0x, 192.1x, 192.2x, 192.3x, 192.8x, 192.9x	C70.xx, C71.xx, C72.xx
Colorectal Cancer	153.xx, 154.0x, 154.1x, 154.8x	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	140.xx, 141.0x, 141.1x, 141.2x, 141.3x, 141.4x, 141.5x, 141.6x, 141.8x, 141.9x, 142.0x, 142.1x, 142.2x, 142.8x, 142.9x, 143.xx, 144.xx, 145.0x, 145.1x, 145.2x, 145.3x, 145.4x, 145.5x, 145.6x, 145.8x, 145.9x, 146.0x, 146.1x, 146.2x, 146.3x, 146.4x, 146.5x, 146.6x, 146.7x, 146.8x, 146.9x 147.xx, 148.0x, 148.1x, 148.2x, 148.3x, 148.8x, 148.9x, 149.xx, 160.0x, 160.1x, 160.2x, 160.3x, 160.4x, 160.5x, 160.8x, 160.9x, 161.xx, 195.0x	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Kidney Cancer	189.0x	C64.xx
Liver Cancer	155.xx, 156.0x, 156.1x, 156.2x, 156.8x, 156.9x	C22.xx, C23.xx, C24.xx
Lung Cancer	162.0x, 162.2x, 162.3x, 162.4x, 162.5x, 162.8x, 162.9x, 165.xx	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	202.80, 202.81, 202.82, 202.83, 202.84, 202.85, 202.86, 202.87, 202.88, 203.80,	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x

	203.82, 200.0x, 200.1x, 200.2x, 200.3x, 200.4x, 200.5x, 200.6x, 200.7x, 200.8x, 201.xx, 202.0x, 202.1x, 202.2x, 202.4x, 202.7x, 273.3x	
Pancreatic Cancer	157.xx	C25.xx
Prostate Cancer	185.xx	C61.xx
Upper GI Cancer	150.xx, 151.xx, 152.xx	C15.xx, C16.xx, C17.xx
Uterine Cancer	179.xx, 182.xx	C54.xx, C55.xx

CMS would maintain the list of ICD-10 codes for included cancer types under the RO Model on the RO Model website. CMS states that it would communicate changes via the RO Model website and written correspondence to RO participants no later than 30 days prior to each PY. Any changes to the diagnosis codes for the included cancer types would be announced as part of the CMS standard process for announcing coding changes.

CMS invites comments on its proposal.

b. Episode Length and Trigger

CMS proposes that the length of an episode under the RO Model be 90 days. Day 1 would be the date of service that a Professional participant or Dual participant furnishes the initial treatment planning service (included in the PC), provided that a Technical participant or Dual participant furnishes an RT delivery service (included in the TC) within 28 days of the treatment planning service. CMS determined based on its analyses that about 99 percent of beneficiaries completed their course of radiation within 90 days of their initial treatment planning service. CMS also found that the average Medicare spending for radiation treatment drops significantly 9 to 11 weeks following the initial RT services for most diagnoses, including prostate, breast, lung, and head and neck cancers.

CMS proposes that an episode would be triggered only if both of the following conditions are met: (1) there is an initial treatment planning service (that is, submission of treatment planning HCPCS codes 77261-77263, all of which would be included in the PC) furnished by a Professional participant or a Dual participant; and (2) at least one radiation treatment delivery service is furnished by a Technical participant or a Dual participant within the following 28 days. An episode that is triggered would end 89 days after the date of the initial treatment planning service, creating a 90-day episode.

If a beneficiary receives an initial treatment planning service but does not receive RT treatment from a Technical participant or Dual participant within 28 days, then the requirements for triggering an episode would not be met. Thus, no RO episode will have occurred, and the proposed incomplete episode policy would take effect. In those cases where the TC of an episode is not furnished by a Dual participant, the Professional participant would provide the Technical participant with a signed 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.

CMS proposes that another episode may not be triggered until at least 28 days after the previous episode has ended. It notes that 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. CMS refers to the 28-day period after an episode has ended, during which time a RO participant would bill for medically necessary RT services furnished to a RO beneficiary in accordance with Medicare FFS billing rules, as the "clean period." It proposes to codify the term "clean period" at §512.205 of its regulations.

If clinically appropriate, a RO participant may initiate another episode for the same beneficiary after the 28-day clean period has ended. CMS states that the Innovation Center would monitor the extent to which services are furnished outside of 90-day episodes, including during clean periods, and for the number of RO beneficiaries who receive RT in multiple episodes.

CMS seeks comment on its proposals.

c. Proposed Included RT Services

CMS proposes that the RO Model would include most RT services furnished in HOPDs and freestanding radiation therapy centers. Services furnished within an episode of RT usually follow a standard, clearly defined process of care. CMS proposes to include treatment planning, technical preparation and special services, treatment delivery, and treatment management as the RT services in an episode paid for by CMS, and propose to codify this at §512.235.

The subcomponents of RT services are described in the table below:

Term	Definition
Consultation	A consultation is an evaluation and management (E&M) service, which typically consists of a medical exam, obtaining a problem-focused medical history, and decision making about the patient's condition/care.
Treatment planning	Treatment planning tasks include determining a patient's disease bearing areas, identifying the type and method of radiation treatment delivery, specifying areas to be treated, and selecting radiation therapy treatment techniques. Treatment planning often includes simulation (the process of defining relevant normal and abnormal target anatomy and obtaining the images and data needed to develop the optimal radiation treatment process). Treatment planning may involve marking the area to be treated on the patient's skin, aligning the patient with localization lasers, and/or designing immobilization devices for precise patient positioning.
Technical preparation and special services	Technical preparation and special services include radiation dose planning, medical radiation physics, dosimetry, treatment devices, and special services. More specifically, these services also involve building treatment devices to refine treatment delivery and mathematically determining the dose and duration of radiation therapy. Radiation oncologists frequently work with dosimetrists and medical physicists to perform these services.
Radiation treatment delivery services	Radiation treatment is usually furnished via a form of external beam radiation therapy or brachytherapy, and includes multiple modalities. Although treatment generally occurs daily, the care team and patient determine the specific timing and amount of treatment. The treating physician must verify and document the accuracy of treatment delivery as related to the initial treatment planning and setup procedure.

Treatment management:	Radiation treatment management typically includes review of port films, review and changes to dosimetry, dose delivery, treatment parameters, review of patient's setup, patient examination, and follow-up care.

CMS is not proposing to include E&M services as part of the episode payment. RO participants would continue to bill E&M services under Medicare FFS. As part of its rational, CMS states that other radiation services are typically only furnished by radiation oncologists and their team, whereas E&M services are furnished by a wide range of physician specialists (for example, primary care, general oncology, others). Its data analysis shows that when consultations and visits were included for an analysis of professional RT services during 2014-2016, only 18 percent of episodes involved billing by a single entity (TIN or CCN) as opposed to 94 percent of episodes when consultations and visits were excluded.

CMS proposes to exclude low volume RT services from the RO Model. These include certain brachytherapy surgical procedures, neutron beam therapy, hyperthermia treatment, and radiopharmaceuticals. These services are being excluded because they are not offered in sufficient amounts for purposes of evaluation.

CMS also proposes to include brachytherapy radioactive elements, rather than omit these services, from the episodes because they are generally furnished in HOPDs and the hospitals are usually the purchasers of the brachytherapy radioactive elements. When not furnished in HOPDs, these services are furnished in ASCs, which CMS proposes to exclude from the Model.

CMS compiled a list of HCPCS codes that represent treatment planning, technical preparation and special services, treatment delivery, and treatment management for the included modalities. RT services included on this list are referred to as "RO Model Bundled HCPCS" when they are provided during a RO Model episode since payment for these services is bundled into the RO episode payment. This list of services is included in Table 2 in the proposed rule (and reproduced in the Appendix at the end of this summary).

CMS propose to codify at §512.270 that these RT services would not be paid separately during an episode. CMS notes that it may add, remove, or revise any of the bundled HCPCS codes included in the RO Model and would maintain a list of the HCPCS codes included in the RO Model on the RO Model website.

CMS invites comments on its proposal, including comments on the proposed inclusion of brachytherapy radioactive sources in the episodes.

d. Proposed Included Modalities

CMS proposes to include the following RT modalities in the RO Model: various types of external beam RT, including 3-dimensional conformal radiotherapy (3DCRT), intensity-modulated radiotherapy (IMRT), stereotactic radiosurgery (SRS), stereotactic body radiotherapy (SBRT), and proton beam therapy (PBT); intraoperative radiotherapy (IORT); image-guided radiation therapy (IGRT); and brachytherapy. CMS proposes to include all of these modalities because they are the most commonly used to treat the 17 included cancer types and including these modalities would allow it to determine whether the RO Model is able to impact RT holistically rather than testing a limited subset of services.

CMS invites comment its proposal to include PBT in the RO Model. CMS also invites comment on whether or not the RO Model should include RO beneficiaries participating in federally-funded, multi-institution, randomized control clinical trials for PBT.

6. Proposed Pricing Methodology

   a. Overview

CMS describes in this section the data and processes used to determine the amounts for participant-specific professional episode payments and participant-specific technical episode payments for each included cancer type. It proposes to define the terms "participant-specific professional episode payment" and "participant-specific technical episode payment" at §512.205 of its regulations, as stated below:

- Participant-specific professional episode payment – payment made by CMS to a Professional participant or Dual participant for the provision of the professional component of RT services furnished to a RO beneficiary during an episode.

- Participant-specific technical episode payment - payment made by CMS to a Technical participant or Dual participant for the provision of the technical component of RT services furnished to a RO beneficiary during an episode.

There are eight primary steps to the proposed pricing methodology.

Step 1	Create a set of national base rates for the PC and TC of the included cancer types, yielding 34 different national base rates (i.e., historical average cost)
Step 2	Apply a trend factor to the 34 different national base rates to update those amounts to reflect current trends in payment for RT services and the volume of those services outside of the RO Model under OPPS and PFS
Step 3	Adjust the 34 now-trended national base rates to account for each RO Participant's historical experience and case-mix history.
Step 4	Adjust payment by applying a discount factor to reserve savings for Medicare and reduce beneficiary cost-sharing.
Step 5	Adjust payment by applying an incorrect payment withhold, and either a quality withhold or a patient experience withhold, depending on the type of component the RO participant furnished under the model.
Step 6	Apply geographic adjustments to payments
Step 7 & Step 8	Apply beneficiary coinsurance and a 2 percent adjustment for sequestration to the trended national base rates that have been adjusted

Within its description of these steps, CMS defines certain terms. Within Step 5, CMS defines adjustment of payment by applying an incorrect payment withhold. The incorrect payment withhold would reserve money for purposes of reconciling duplicate RT services and incomplete episodes during the reconciliation process, which CMS discuss further in section III.C.11. CMS proposes to define the term "duplicate RT service" (at §512.205) to mean any included RT service (as identified at §512.235) that is furnished to a single RO beneficiary by a RT provider or RT supplier or both that did not initiate the PC or TC of that RO beneficiary after the episode.

CMS also includes its proposed definition of an "incomplete episode" in this section. An incomplete episodes is defined as an episode that does not occur because: (1) a Technical participant or a Dual participant does not furnish a technical component to a RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an RT treatment planning service to that RO beneficiary; or (2) traditional Medicare stops being the primary payer at any point during the relevant 90-day period the RO beneficiary; or (3) a RO beneficiary stops meeting the beneficiary population criteria under §512.215(a) or triggers the beneficiary exclusion criteria under §512.215(b) before the technical component of an episode initiates.

Each is described in more detail below.

b. Proposal to Construct Episodes using Medicare FFS Claims and Calculate Episode Payments

CMS proposes to construct episodes based on dates of service for Medicare FFS claims paid during the CYs 2015-2017 as well as claims that are included under an episode where the initial treatment planning service occurred during the CYs 2015 – 2017. CMS would exclude those episodes that do not meet its proposed criteria (as described in III.C.3.d).

CMS proposes to convert 2015 payment amounts to 2017 by multiplying: (a) the 2015 payment amounts by the ratio of (b) average payment amounts for episodes that initiated in 2017 to (c) average payment amounts for episodes that initiated in 2015. CMS would apply this same process for episodes starting in 2016. CMS would weight the most recent observations more heavily than those that occurred in earlier years: 20 percent for 2015, 30 percent for 2016, and 50 percent for 2017 for episodes initiated in each of these years.

CMS clarifies that only episodes from the HOPD setting would be used to calculate national base rates and for use in case-mix regression models. For purposes of calculating the historical experience adjustment, CMS would use average payments of all episodes nationally from both the HOPD and freestanding radiation therapy center settings.

c. Proposed National Base Rates

CMS proposes to define the term" national base rate" to mean the total payment amount for the relevant component of each episode before application of the trend factor, discount factor, adjustments, and applicable withholds for each of the proposed included cancer types. CMS proposes to codify this term at §512.205 of its regulations.

The national base rates represent the historical average cost for an episode of care for each of the included cancer types. The calculation of these rates would be based on Medicare FFS claims

paid during the CYs 2015-2017 that are included under an episode where the initial treatment planning service occurred during the CYs 2015-2017. If an episode straddles CYs, the episode and its claims are counted in the calendar year for which the initial treatment planning service is furnished.

CMS excludes those episodes that do not meet certain criteria. In brief, the following episodes would be excluded from calculations to determine the national base rates:

- Episodes with any services furnished by a CAH;
- Episodes without positive (>$0) total payment amounts for professional services or technical services;
- Episodes assigned a cancer type not identified as cancer types that meet its criteria (see Table 1);
- Episodes that are not assigned a cancer type;
- Episodes with RT services furnished in Maryland, Vermont, or a U.S. Territory;
- Episodes in which a PPS-exempt cancer hospital furnishes the technical component (is the attributed
- technical provider); and
- Episodes in which a Medicare beneficiary does not meet the eligibility criteria

From those episodes, CMS propose to calculate the amount CMS paid on average to providers for the PC and TC for each of the included cancer types in the HOPD setting, creating the RO Model's national base rates. Specifically, CMS proposes using episodes that meet the following criteria: (1) episodes initiated in 2015-2017; (2) episodes attributed to a HOPD; and (3) during an episode, the majority of technical services were provided in a HOPD (that is, more technical services were provided in a HOPD than in a freestanding radiation therapy center). CMS concludes that OPPS payments have been more stable over time and have a stronger empirical foundation than those under the PFS, as the OPPS payment amounts are generally derived from information from hospital cost reports.[20] CMS states that unless a broad rebasing is done after a later PY in the model, these national base rates would be fixed throughout the model performance period.

CMS states that it would publish these amounts no later than 30 days before the start of the PY in which payments would be made. Its proposed national base rates for the model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3 in the proposed rule (reproduced below).

TABLE 3 – National Base Rates by Cancer Type (in 2017 dollars)

RO Model-Specific Placeholder Codes[21]	Professional or Technical	Cancer Type	Base Rate
MXXXX	Professional	Anal Cancer	$2,968
MXXXX	Technical	Anal Cancer	$16,006

[20] This implies that national base rates derived for the technical component are derived primarily from OPPS data. Data for the professional component would have been derived from Medicare PFS claims.
[21] The final HCPCS codes specific to the RO Model would be published in the CY2020 Level 2 HCPCS code file.

TABLE 3 – National Base Rates by Cancer Type (in 2017 dollars)			
RO Model-Specific Placeholder Codes[21]	**Professional or Technical**	**Cancer Type**	**Base Rate**
MXXXX	Professional	Bladder Cancer	$2,637
MXXXX	Technical	Bladder Cancer	$12,556
MXXXX	Professional	Bone Metastases	$1,372
MXXXX	Technical	Bone Metastases	$5,568
MXXXX	Professional	Brain Metastases	$1,566
MXXXX	Technical	Brain Metastases	$9,217
MXXXX	Professional	Breast Cancer	$2,074
MXXXX	Technical	Breast Cancer	$9,740
MXXXX	Professional	Cervical Cancer	$3,779
MXXXX	Technical	Cervical Cancer	$16,955
MXXXX	Professional	CNS Tumor	$2,463
MXXXX	Technical	CNS Tumor	$14,193
MXXXX	Professional	Colorectal Cancer	$2,369
MXXXX	Technical	Colorectal Cancer	$11,589
MXXXX	Professional	Head and Neck Cancer	$2,947
MXXXX	Technical	Head and Neck Cancer	$16,708
MXXXX	Professional	Kidney Cancer	$1,550
MXXXX	Technical	Kidney Cancer	$7,656
MXXXX	Professional	Liver Cancer	$1,515
MXXXX	Technical	Liver Cancer	$14,650
MXXXX	Professional	Lung Cancer	$2,155
MXXXX	Technical	Lung Cancer	$11,451
MXXXX	Professional	Lymphoma	$1,662
MXXXX	Technical	Lymphoma	$7,444
MXXXX	Professional	Pancreatic Cancer	$2,380
MXXXX	Technical	Pancreatic Cancer	$13,070
MXXXX	Professional	Prostate Cancer	$3,228
MXXXX	Technical	Prostate Cancer	$19,852
MXXXX	Professional	Upper GI Cancer	$2,500
MXXXX	Technical	Upper GI Cancer	$12,619
MXXXX	Professional	Uterine Cancer	$2,376
MXXXX	Technical	Uterine Cancer	$11,221

d. Proposal to Apply Trend Factors to National Base Rates

CMS proposes to apply a trend factor to the 34 different national base rates in Table 3. For each PY, CMS would calculate separate trend factors for the PC and TC of each cancer type using data from HOPDs and freestanding radiation therapy centers not participating in the model. It proposes that these calculated trend factors be updated and applied to the national base rates prior to the start of each PY (for which they would apply).

For the PC and TC of each included cancer type, CMS' proposed approach would calculate a ratio of: (a) volume-weighted FFS payment rates for RT services included in that component for the specific cancer type in the upcoming PY (that is, the numerator) to (b) volume weighted FFS payment rates for RT services included in that component for the specific cancer type in the most recent baseline year (that is, the denominator), which would be FFS rates from 2017.

For example, for PY1, the calculation for the trend factor would be as follows:

2020 Trend factor = (2017 volume * 2020 corresponding FFS rates as paid under OPPS or PFS) / (2017 volume * 2017 corresponding FFS rates as paid under OPPS or PFS)

CMS would then multiply: (a) the trend factor for each national base rate by (b) the corresponding national base rate for the PC and TC of each cancer type from Step 1, yielding 34 trended national base rates. The trended national base rates for 2020 would be made available on the RO Model's website once CMS issues the CY 2020 OPPS and PFS final rules that establish payment rates for the year. CMS notes that to the extent that it introduces new HCPCS codes that CMS determines should be included in the RO Model, it proposes to cross-walk the volume based on the existing set of codes to any new set of codes as it does in the PFS rate-setting process.

e. Proposal to Adjust for Case Mix and Historical Experience

(1) Proposed Case Mix Adjustments

CMS proposes a case-mix adjustment to account for differences in patient characteristics that are beyond a provider's control. CMS states that it tested and evaluated potential case-mix variables and found several variables (cancer type; age; sex; presence of a major procedure; death during the first 30 days, second 30 days, or last 30 days of the episode; and presence of chemotherapy) to be strongly and reliably predictive of cost under the FFS payment system.

Based on the results of this testing, CMS proposes to develop a case mix adjustment, measuring the occurrence of the case mix variables among the beneficiary population that each RO participant has treated historically (that is, among beneficiaries whose episodes have been attributed to the RO participant during 2015-2017) compared to the occurrence of these variables in the national beneficiary profile.[22]

CMS states that it would first Winsorize, or cap, the episode payments in the national beneficiary profile at the 99th and 1st percentiles by cancer type. CMS states that it would use Ordinary Least Squares (OLS) regression models, one for the PC and one for the TC, to identify the

[22] The national beneficiary profile is developed from the same episodes used to determine the Model's national base rates, that is 2015-2017 episodes attributed to all HOPDs nationally.

relationship between episode payments and the case mix variables. The regression models are intended to measure how much of the variation in episode payments can be attributed to variation in the case mix variables.

From the coefficients, CMS would determine a RO participant's predicted payments, or the payments predicted under the FFS payment system for an episode of care as a function of the characteristics of the RO participant's beneficiary population. For PY1, these predicted payments would be based on episode data from 2015 to 2017. These predicted payments would be summed across all episodes attributed to the RO participant to determine a single predicted payment for the PC or the TC.

CMS would then compare the RO participant's predicted payments to its expected payments. Expected payment would be the payments expected when a participant's case mix (other than cancer type) is not considered in the calculation. The difference between a RO participant's predicted payment and a RO participant's expected payment, divided by the expected payment, would constitute either the PC or the TC case mix adjustment for that RO participant. Mathematically this would be expressed as follows:

Case mix adjustment = (Predicted payment – Expected payment) / Expected payment

CMS clarifies that neither the national beneficiary profile nor the regression model's coefficients would change over the course of the model's performance period. The coefficients would be applied to a rolling 3-year set of episodes attributed to the RO participant so that a RO participant's case mix adjustments take into account more recent changes in the case mix of their beneficiary population. For example, CMS states that it would use data from 2015-2017 for PY1, data from 2016-2018 for PY2, data from 2017-2019 for PY3, etc.

CMS does not, however, provide details on the regression models, such as the coefficients or provide illustrative examples of these calculations, in the proposed rule.

(2) Proposed Historical Experience Adjustments and Efficiency Factor

CMS also proposes an efficiency factor based on historical experience. To determine historical experience adjustments for a RO participant CMS proposes using episodes attributed to the RO participant that were initiated during 2015-2017. CMS would calculate separate adjustments for the PC and the TC using all episodes nationally using Winsorization thresholds attributed to the RO participant at the 99th and 1st percentiles.

Mathematically, for episodes attributed to the RO participant, this would be expressed as:

Historical experience adjustment = (Winsorized payments – Predicted payments) / Expected payments

If based on the proposed calculation, the historical experience adjustment has a value equal to or less than 0.0, then the RO participant would be categorized as historically efficient compared to the payments predicted under the FFS payment system for an episode of care. If the historical experience adjustment has a value greater than 0.0, then the RO participant would be categorized as historically inefficient. Efficiency factor is the weight that a RO participant's historical experience adjustments are given over the course of the RO Model's performance period.

CMS proposes that for RO participants with historical experience adjustments with a value greater than 0.0, the efficiency factor would decrease over time to reduce the impact of historical practice patterns on payment. More specifically, for RO participants with a PC or TC historical experience adjustment with a value greater than 0.0, the efficiency factor would be 0.90 in PY1, 0.85 in PY2, 0.80 in PY3, 0.75 in PY4 and 0.70 in PY5. For those RO participants with a PC or TC historical experience adjustment with a value equal to or less than 0.0, the efficiency factor would be fixed at 0.90 over the RO Model's performance period.

(3) Proposal to Apply the Adjustments

To apply the case mix adjustment, the historical experience adjustment, and the efficiency factor to the trended national base rates CMS states that it would multiply: (a) the corresponding historical experience adjustment by (b) the corresponding efficiency factor, and then add (c) the corresponding case mix adjustment and (d) the value of one. This formula creates a combined adjustment that can be multiplied with the national base rates. Mathematically this would be expressed as:

Combined Adjustment = (Historical experience adjustment * Efficiency factor) + Case mix adjustment + 1.0

The combined adjustment would then be multiplied by the corresponding trended national base rate from Step 2 for each cancer type. CMS would repeat these calculations for the corresponding case mix adjustment, historical experience adjustment, and efficiency factor for the TC, yielding a total of 34 RO participant-specific episode payments for Dual participants and a total of 17 RO participant-specific episode payments for Professional participants and Technical participants.

CMS proposes to use these case mix adjustments, historical experience adjustments, and efficiency factors to calculate the adjustments under the RO Model's pricing methodology.

(4) Proposal for HOPD or Freestanding Radiation Therapy Center with Fewer than Sixty Episodes

CMS proposes that if a HOPD or freestanding radiation therapy center (identified by a CCN or TIN) furnishes RT services during the model performance period and is required to participate, but has fewer than 60 episodes attributed to it during the 2015-2017 period, then the RO participant's participant-specific professional episode payment and technical episode payment amounts would equal the trended national base rates in PY1. CMS would repeat this determination for PY2-PY5.

(5) Proposal to Apply Adjustments for HOPD or Freestanding Radiation Therapy Center with a Merger, Acquisition, or Other New Clinical or Business Relationship, with or without a CCN or TIN Change

CMS proposes that that a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2024 meets the RO Model's proposed eligibility requirements. If the new TIN or CCN begins to furnish RT services within a selected CBSA, then it must participate in the model. CMS states it is proposing this policy in

order to prevent HOPDs and freestanding radiation therapy centers from engaging in mergers, acquisitions, or other new clinical or business relationships to avoid participating.

CMS also proposes the RO Model requires advanced notification (same as proposed at §512.180(c)) so that appropriate adjustments are made to episode payment amounts). RO participants must also provide a notification regarding a new clinical relationship that may or may constitute a change in control. If there is sufficient historical data from the entities merged, absorbed, or otherwise changed as a result of this new clinical or business relationship, then this data would be used to determine adjustments for the new or existing TIN or CCN.

f. Proposal to Apply a Discount Factor

After applying participant-specific adjustments to the trended national base rates, CMS proposes to next deduct a percentage discount from those amounts for each performance year. The discount factor would not vary by cancer type. The discount factor for the PC would be 4 percent. The discount factor for the TC would be 5 percent. CMS believes these figures strike an appropriate balance in creating savings for Medicare while not creating substantial financial burden on RO participants with respect to reduction in payment.

CMS proposes to apply these discount factors to the RO participant-adjusted and trended payment amounts for each of the RO Model's performance years.

g. Proposal to Apply Withholds

CMS proposes to withhold a percentage of the total episode payments, that is the payment amounts after the trend factor, adjustments, and discount factor have been applied to the national base rates, to address various payment issues, and to incentive quality care. These are discussed in this section.

(1) Proposed Incorrect Payment Withhold

CMS proposes to withhold 2 percent of the total episode payments for both the PC and TC of each cancer type. This 2 percent would reserve money to address overpayments that may result from two situations: (1) duplicate RT services and (2) incomplete episodes. CMS proposes a withhold for these circumstances in order to decrease the likelihood of CMS needing to recoup payment. Such a circumstance would increase administrative burden on CMS and potentially disrupt a RO participant's cash flow. CMS analysis of claims data shows that duplicate RT services and incomplete services are uncommon (2 and 6 percent, respectively). CMS would use the annual reconciliation process to determine whether a RO participant is eligible to receive back the full 2 percent withhold amount, a portion of it, or must repay funds to CMS.

CMS proposes to define the following terms at §512.205 of its regulations.

- Repayment amount - amount owed by a RO participant to CMS, as reflected on a reconciliation report.
- Reconciliation report - annual report issued by CMS to a RO participant for each performance year, which specifies the RO participant's reconciliation payment amount or repayment amount

(2) Proposed Quality Withhold

CMS also proposes to apply a 2 percent quality withhold for the PC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied. Professional participants and Dual participants would be able to earn back up to the 2 percent withhold amount each performance year based on their aggregate quality score (AQS). This feature allows the model to meet quality criterion for an Advanced APM. CMS would use the annual reconciliation process to determine how much of the 2 percent withhold a participant would receive back.

CMS also proposes to define the term "AQS" at §512.205 of its regulations to mean the numeric score calculated for each RO participant based on its performance on, and reporting of, proposed quality measures and clinical data, which is used to determine the amount of a RO participant's quality reconciliation payment amount.

(3) Proposed Patient Experience Withhold

CMS proposes to withhold 1 percent for the TC to the applicable trended national base rates after the case mix and historical experience adjustments and discount factor have been applied starting in PY3 (January 1, 2022 through December 31, 2022) to account for patient experience in the RO Model. Technical participants and Dual participants would be able to earn back up to the full amount of the patient experience withhold for a given PY based on their results from the patient-reported Consumer Assessment of Healthcare Providers and Systems (CAHPS® Cancer Care Survey) Cancer Care Survey for Radiation Therapy. The annual reconciliation process, as with the incorrect payment and quality withholds, would determine how much of the 1 percent withhold a participant would receive back.

CMS proposes that the incorrect payment withhold, the quality withhold, and the patient experience withhold would be included in the RO Model's pricing methodology.

h. Proposal to Adjust for Geography

CMS proposes to adjust payments for difference in costs of providing care in different geographic areas. The geographic adjustment applied—either the OPPS or the PFS adjustment – would depend on where the RT services were furnished. CMS would adjust the trended national base rates that have been adjusted for each RO participant's case mix, historical experience and after which the discount rate and withholds have been applied, for local cost and wage indices based on where RT services are furnished, pursuant to existing geographic adjustment processes in the OPPS and PFS. Geographic adjustments would be calculated after CMS submits RO Model payment files to the Medicare Administrative Contractors that contain RO participant-specific calculations of payment from steps (a) through (g).

With respect to the OPPS adjustment, OPPS automatically applies a wage index adjustment based on the current year post-reclassification hospital wage index to 60 percent (the labor-related share) of the OPPS payment rate. No additional changes to the OPPS Pricer are needed to ensure geographic adjustment.

The PFS geographic adjustment has three components that are applied separately to the three RVU components that underlie the PFS—Work, practice expense (PE) and malpractice (MP).

To calculate a locality-adjusted payment rate for the RO participants paid under PFS, CMS states that it would create a set of RO Model-specific RVUs using the national (unadjusted) payment rates for each HCPCS code of the included RT services for each cancer type included in the RO Model. The RVU shares would not vary by cancer type.

Table 4 in the proposed rule (reproduced below) provides the proposed relative weight of the RO Model-specific RVUs share s for the PC and TC that would be used to apply the PFS GPCIs. Details of how these shares were derived are provided in the proposed rule.

Table 4 RVU Shares

Professional Component			Technical Component		
WORK	**PE**	**MP**	**WORK**	**PE**	**MP**
0.66	0.30	0.04	0.00	0.99	0.01

i. Proposal to Apply Coinsurance

CMS proposes to calculate the coinsurance amount for a RO beneficiary after applying all adjustments (expect for sequestration). Under current policy, Medicare FFS beneficiaries are generally required to pay 20 percent of the allowed charge for services furnished by HOPDs and physicians (for example, those services paid for under the OPPS and PFS, respectively). This policy would remain the same under the RO Model. RO beneficiaries would pay 20 percent of each of the bundled PC and TC payments for their cancer type, regardless of what their total coinsurance payment amount would have been under the FFS payment system.

CMS notes that, depending on the choice of modality and number of fractions administered by the RO participant during the course of treatment, the coinsurance payment amount of the bundled rate may occasionally be higher than what a beneficiary or secondary insurer would otherwise pay under Medicare FFS.

CMS also recognizes that because episode payment amounts under the RO Model would include payments for RT services that would likely be provided over multiple visits, the beneficiary coinsurance payment for each of the episode's payment amounts would likewise be higher than it would otherwise be for a single RT service visit. CMS suggests that for RO beneficiaries who do not have a secondary insurer, it would encourage RO participants to collect coinsurance for services furnished under the RO Model in multiple installments via a payment plan (provided the RO participants would inform patients of the installment plan's availability only during the course of the actual billing process).

CMS would continue to apply the limit on beneficiary liability for copayment for a procedure to the trended national base rates that concern the TC after adjustments have been applied, as specified in Section 1833(t)(8)(C)(i) of the Social Security Act.[23]

[23] This provision states that the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established for that year.

CMS invites comment on its proposal to apply the standard coinsurance of 20 percent.

j. Example of Participant-Specific Professional Episode Payment and Participant-Specific

CMS provides an example calculation illustrating the eight steps. This is shown in Table 5 of the proposed rule (reproduced here) and details the participant-specific professional episode payment paid by CMS to a single TIN for the furnishing of RT professional services to RO beneficiary for an episode of lung cancer. This example does not include any withhold amount that the RO participant would be eligible to receive back or repayment if more money is needed.

Table 5: Example: Participant-Specific Professional Episode Payment for Lung Cancer

	Professional Component	
	Amount	**Formula**
National Base Rate (a)	$2,155.00	
Trend Factor (b)	1.04	
Subtotal (c)	$2,241.20	c = a * b
Case Mix Adjustment (d)	0.02	For example (102-100) / 100
Historical Experience Adjuster (e)	0.14	For example (116-102) / 100
Year 1 Efficiency Factor (f)	0.90	
Adjustments combined (g)	1.15	g = d + (e * f) + 1
Subtotal (h)	$2,568.42	h = c * g
Discount Factor (i)	0.96	
Subtotal (j)	$2,465.68	j = i * h
Withhold #1 (Incorrect Payment) (k)	0.98	
Withhold #2 (Quality Performance) (l)	0.98	
Subtotal2 (m)	$2,368.04	m = j * k * l
Geographic Adjustment (n)	1.02	
2019 Total Episode Payment to Participant including Coinsurance owed by RO beneficiary (o)	$2,415.40	o = m * n
20% Beneficiary Coinsurance Determined (p)	**$483.08**	**p = o * 0.20**
80% Participant Payment (q)	$1,932.32	q = o * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (r) [r = participant-specific professional episode payment]	$1,893.67	r = q * 0.98
Episode Payment 1 (s)*	**$946.84**	**s = r / 2**
Episode Payment 2 (t)*	**$946.84**	**t = r / 2**

^ All numbers are rounded to two decimal places.

Table 6 in the proposed rule details an illustrative example for a participant-specific technical episode payment.

CMS invites comment on its proposed pricing methodology.

7. Proposed Professional and Technical Billing and Payment

CMS proposes to pay for complete episodes in two installments: one tied to when the episode

begins, and another tied to when the episode ends. Under this proposed policy, a Professional participant would receive two installment payments for furnishing the PC of an episode, a Technical participant would receive two installment payments for furnishing the TC of an episode, and a Dual participant would receive two installment payments for furnishing the PC and TC of an episode. CMS believes that two payments reduce the amount of money that may need to be recouped due to incomplete episodes and reduces the likelihood that the limit on beneficiary liability for copayment for a procedure provided in a HOPD (as described in section 1833(t)(8)(C)(i) of the Act) is met.

CMS states that to reduce burden on RO participants, it proposes to make the prospective episode payments for RT services covered under the RO Model using the existing Medicare FFS claims processing systems. Any changes needed would be made using the standard Medicare Fee for Service operations policy related Change Requests (CRs). Local coverage determinations (LCDs), which provide information about the reasonable and necessary conditions of coverage allowed, would still apply to all RT services provided in an episode.

Professional participants and Dual participants would be required to bill a new model specific HCPCS code and a modifier indicating the start of an episode (SOE modifier) for the PC once the treatment planning service is furnished. CMS would develop a new HCPCS code (and modifiers, as appropriate) for the PC of each of the included cancer types under the Model. The two payments for the PC of the episode would cover all RT services provided by the physician during the episode. Payment for the PC would be made through the PFS and would only be paid to physicians (as identified by their respective TINs). A Professional participant or Dual participant must bill the same RO Model-specific HCPCS code that initiated the episode with a modifier indicating the end of an episode (EOE) after the end of the 90-day episode. This would indicate that the episode has ended. Upon submission of a claim with a RO Model-specific HCPCS codes and EOE modifier CMS would pay the second half of the payment for the PC of the episode to the Professional participant or Dual participant.

Under its proposed billing policy, a Technical participant or a Dual participant that furnishes the TC of an episode must bill a new model-specific HCPCS code with a SOE modifier. CMS would pay the first half of the payment for the TC of the episode when a Technical participant or Dual participant furnishes the TC of the episode and bills for it using model specific HCPCS code with a SOE modifier. CMS would pay the second half of the payment for the TC of the episode after the end of the episode. The Technical participant or Dual participant must bill the same RO Model-specific HCPCS code with an EOE modifier that initiated the episode. This would indicate that the episode has ended. Payment for the TC would be made through either the OPPS or PFS to the Technical participant or Dual participant that furnished TC of the episode.

RO participants would be required to submit encounter data (no-pay) claims that include all RT services identified on the RO Model Bundled HCPCS list (Table 2) as services are furnished and would otherwise be billed under the Medicare FFS systems. CMS states that it will monitor trends in utilization of RT services during the model and that these data would be used for evaluation and model monitoring, among other uses.

CMS discusses how it would handle certain circumstances with respect to the episode payment. These are described in the table below:

Event	Payment Policy
RO participant provides clinically appropriate RT services during the 28 days after an episode ends	RO participant must bill Medicare FFS for those RT services. A new episode may not be initiated during the 28 days after an episode ends – this period is referred to as the "clean period."
RO beneficiary changes RT provider or RT supplier after the SOE claim has been paid	CMS would subtract the first episode payment paid to the RO participant – adjustment would occur during the annual reconciliation process. The subsequent provider or supplier would bill FFS for furnished RT services.
Beneficiary dies, enters hospice, or chooses to defer treatment after the PC has been initiated and the SOE claim paid but before the TC of the episode has been initiated (also referred to as an incomplete episode	CMS would subtract the first episode payment paid to the Professional participant or Dual participant from the FFS payments owed to that RO participant – adjustment would occur during the annual reconciliation process.
Traditional Medicare stops being the primary payer after the SOE claims for the PC and TC were paid	Any submitted EOE claims would be returned and the RO participant(s) would only receive the first episode payment, regardless of whether treatment was completed.
Beneficiary dies or enters hospice after both PC and TC of the episode have been initiated	RO participant(s) may bill EOE claims and be paid the second half of the episode payment amounts regardless of whether treatment was completed. This is because death and hospice are included in the case mix adjuster.
Claim is submitted with a RO Model-specific HCPCS code for a site of service that is located within one of the randomly selected CBSAs as identified by the service location's ZIP Code, but the CCN or TIN is not yet identified as a RO participant in the claims systems	Claim would be paid using the rate assigned to that RO Model-specific HCPCS code without the adjustments.

CMS states that the list of RO Model-specific HCPCS codes would be made available on the RO Model website prior to the model performance period. In addition, it expects to provide RO participants with additional instructions for billing the RO Model-specific HCPCS codes through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website.

8. Quality

CMS proposes to adopt four quality measures and collect the CAHPS® Cancer Care Radiation Therapy Survey for the RO Model. Three of the four measures are NQF-endorsed process measures and are approved for the Merit-based Incentive System (MIPS). CMS believes all the proposed measures would be appropriate for RT services spanning a 90-day episode period, are applicable to a full range of cancer types, and can be used to accurately measure change or improvements in the quality of RT services.

Table 7 (reproduced below) summarizes the proposed quality measures, level of reporting, and the measure' status as pay-for-reporting or pay-for-performance. CMS proposes requiring Professional and Dual participants to report all quality data for all applicable patients receiving RT services from RO participants based on numerator and denominator specifications for each measure.

CMS considers the RO Model as an Advanced APM and a Merit-based Incentive Payment System (MIPS) APM for the Quality Payment Program (QPP).

Table 7: RO Participant Quality Measure, Clinical Data, and Patient Experience Submission Requirements			
RO Participant Data Submission Requirements	**Level of Reporting**	**Pay-for-Reporting**	**Pay-for-Performance**
1. Oncology: Medical and Radiation – Plan of Care for Pain (NQF #383; CMS Quality ID #144)	Aggregate	N/A	PYs 1-5
2. Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134)	Aggregate	N/A	PYs 1-5
3. Advance Care Plan (NQF 30326; CMS Quality ID #047)	Aggregate	N/A	PYs 1-5
4. Treatment Summary Communication – Radiation Oncology	Aggregate	PYs 1-2	PYs 3-5
5. CAHPS Cancer Care Survey	N/A: Patient-Reported	N/A	PYs 3-5
Clinical Data Elements	Beneficiary-Level	PYs 1-5	N/A

a. Proposed Measure Selection

CMS discusses the reasons for proposing the four quality measures for the RO Model. CMS believes these measures would allow it to quantify the impact of the model on quality of care, RT services and processes, outcomes, patient satisfaction, and organizational structures and systems. In addition, CMS intends for the RO Model to qualify as an Advanced APM and also meet the criteria to be a MIPS APM. CMS believes that the three measures approved by NQF and adopted in MIPS meet the requirements at 42 CFR 414.1415(b)(2). CMS notes that because it has determined there are no currently available or applicable outcome measures for the RO Model included in the MIPS final quality measures list for the Advanced APM's first QP Performance Period, the requirement for an Advanced APM to include at least one outcome measure does not apply. If a relevant outcome measure becomes available, CMS would consider it for inclusion in the RO Model's measure set. CMS intends to adjust the measure set in future PYs by adding new measures or removing measures by notice and comment rulemaking.

CMS describes each measure and its reasons for its proposed selection. Highlights of this discussion for each measure are summarized below.

Proposed Oncology: Medical and Radiation – Plan of Care for Pain (NQF #383; CMS Quality ID #144)

- This measure assesses the percentage of patients, regardless of age, with a diagnosis of cancer who are currently receiving chemotherapy or RT that have moderate or severe pain for which there is a documented plan of care to address pain in the first two visits.[24]
- CMS believes this measure is appropriate because it is specific to a RT episode of care.
    - The current measure is used within the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR), the Oncology Care Model (OCM), and MIPS.
    - The RO Model would adopt the measure according to the most recent version of the specifications, which is under review at the NQF this Fall.
- The measure will be a pay-for-performance measure.

Proposed Preventive Care and Screening: Screening for Depression and Follow-Up Plan (NQF #0418; CMS Quality ID #134)

- This measure assesses the percentage of patients screened for clinical depression with an age-appropriate, standardized tool and who have had a follow-up care plan documented in the medical record.[25]
- CMS believes it is appropriate to screen and treat the potential mental health effects of RT.
    - The current measure is used within the OCM and MIPS.
- This measure will be a pay-for-performance measure.

Proposed Advance Care Plan (NQF #0326; CMS Quality ID #047)

- This measure describes the percentage of patients aged 65 years and older that have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advanced plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care of plan.[26]
- CMS believes this is a cross-cutting measure across all specialties in a variety of settings and is applicable to RT.
    - The measure is used within the OCM and MIPS.
- The measure will be a pay-for-performance measure.

Proposed Treatment Summary Consideration – Radiation Oncology

- This measure is a process measure that assesses the percentage of patients, regardless of age, with a diagnosis of cancer that have undergone brachytherapy or external beam RT who have a treatment summary report in the chart that was communicated to the

[24] Detailed measure specifications are at: https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_133_Registry.pdf.
[25] Detailed measure specifications are at: https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_134_Registry.pdf.
[26] Detailed measure specifications are at https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_047_Registry.pdf.

physician(s) providing continuing care and to the patient within one month of completing treatment.[27]

- CMS believes care coordination and communication between providers during transitions of cancer care are important. Although this measure is not NQF endorsed, and has not been used in CMS quality reporting, it has been used for quality improvement efforts in the oncology field.
- The measure will be a pay-for-reporting measure.
    - CMS expects a benchmark will be established for this measure and it would become a pay-for-performance in PY3.

Proposed CAHPS Cancer Care Survey for Radiation Therapy[28]

- CMS proposes to have a CMS-approved contractor administer the survey beginning April 1, 2020 and ending in 2025 to account for episodes that were completed in the last quarter of 2024.
- CMS states that variations of the CAHPS survey are widely used measures of patient satisfaction and experience of care, and have been used in many CMS programs including MIPS and OCM.
- CMS plans to propose a set of patient experience measures based on the CAHPS Cancer Survey and the measure would be considered a pay-for-performance measure beginning in PY3.

b. Proposed Form, Manner, and Timing for Quality Measure Data Reporting

CMS proposes the following data collection processes for the proposed quality measures:

(i) Require Professional and Dual participants to report aggregated quality measure data, instead of beneficiary-level quality measure data.

(ii) Require the data be reported for all applicable patients on the measure specifications. Data would need to be reported on all patients meeting the denominator specifications for each measure from a Professional or Dual participant and not just Medicare beneficiaries or beneficiaries with radiation episodes under the RO Model.

- CMS notes that any segmentation to obtain data only from the Medicare population would be inconsistent with the measure and add substantial reporting burden to RO participants.
- If a measure is already reported in another program, the measure would need to be reported consistent with the other program's requirements and separately submitted to the RO Model reporting portal consistent with the RO Model requirements.

(iii) The RO Model would not score measures for a given Professional or Dual participant that does not have at least 20 applicable cases. If a measure does not have at least 20 applicable

[27] Detailed measure specifications can be found at http://www.qualityforum.org/QPS/0381.
[28] The CAHPS Cancer Care survey can be found at https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html.

cases, the participant would not have to report the measures.

- A RO participant would enter "N/A-insufficient cases" to indicate an insufficient number of cases exists for a given measure.

(iv) CMS will create a template for Professional and Dual participants to complete for each quality measure and provide a secure portal for data submission.

(v) Quality measure data would need to be submitted annually by March 31 following the end of the previous PY to the RO Model measure specification portal. CMS notes it considered the quality measure reporting deadlines of other CMS programs and the needs of the Model when determining this deadline.

- For PY 1, participants will submit quality measure data for the time period noted in the measure specification. For example, if a measure is calculated on an annual CY basis, participants would not adjust the reporting period to reflect the model time period.
- A schedule for data submission would be posted on the RO Model website.

c. Proposed Clinical Data Collection

CMS proposes that on a pay-for-reporting basis, it would require Professional and Dual participants to report basic, clinical information such as cancer stage, disease involvement, treatment and specific treatment plan information on RO beneficiaries treated for five types of cancer: prostate, breast, lung, bone metastases, and brain metastases. CMS notes this information is not available in claims or captured in the proposed quality measures. CMS will determine the specific data elements and reporting standards prior to the start of the RO Model and would post this information on the RO Model website. CMS will provide education, outreach, and technical assistance.

CMS believes this information is necessary to help eliminate unnecessary or low-value care; develop accurate episode prices; and support clinical monitoring and evaluation of the model. This data may also be used to develop and test new radiation oncology-specific quality measures.

To facilitate data collection, CMS plans to share the proposed clinical data elements and reporting with EHR vendors and the radiation oncology specialty societies prior to the start of the RO Model. CMS notes that providers may also opt to manually extract the necessary data elements. All Professional and Dual participants with RO beneficiaries with the five cancer types would be required to report clinical data through a model-specific data collection system. CMS plans to create a template for RO participants and provide a secure portal data submission.

CMS proposes that all Professional and Dual participants must submit clinical data information biannually, in July and January, each PY for RO beneficiaries with the applicable cancer types that completed their 90-day episode within the previous six months. This requirement would be in addition to the four proposed quality measures.

d. Proposal to Connect Performance on Quality Measures to Payment

Proposed Calculation for the Aggregate Quality Score (AQS)
The AQS would be based on each Professional and Dual participant's:

1. performance on the set of proposed quality measures compared to those measures' 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.

CMS proposes to weight 50 percent of the AQS on successful reporting of required clinical data and 50 percent on quality measure reporting and, where applicable, performance on these measures. Specifically, the proposed weighting for the AQS would be:

Aggregate Quality Score = Quality Measure + Clinical Date

- Quality Measures: 0 to 50 points based on weighted measure scores and reporting
- Clinical Data: 50 points when data is submitted for ≥95% of applicable RO beneficiaries

Quality measures would be scored as pay-for-performance or pay-for-reporting, depending on whether established benchmarks exist. A measure's quality performance benchmark is the performance rate a Professional or Dual participant must achieve to earn quality points for each measure. CMS proposes that pay-for-performance measures would be compared against applicable benchmarks for the MIPS program measures and used to score RO participants performance using MIPS benchmarks.[29] The MIPS program awards up to ten points, including partial points, for each measure and CMS proposes to use a similar scoring methodology to score RO participants quality performance. Thus, if a participant's measured performance is at the MIPS performance level specified for three points, CMS will award the participant three points.

If applicable MIPS benchmarks are not available, CMS proposes using other appropriate national benchmarks. CMS states that it would calculate a Model-specific benchmark from the previous year's historical performance data and if the historical performance data is not available, it would score the measure as pay for reporting. CMS intends to specify quality measure data reporting requirements on the RO Model website.

Professional and Dual participants that report pay-for-reporting measures in the form, time, and manner specified in the measure specification would receive ten points for the measure. Participants that do not submit the measure as specified would receive zero points. For PY1, CMS proposes that the Treatment Summary Communication measure would be the only pay-for-reporting measure.

The total points awarded for each measure would also depend on the measure's weight. CMS proposes to weight all the proposed quality measures (both pay-for-performance and pay-for-reporting) equally and aggregate them as half of the AQS. CMS would award up to 10 points for each measure and then recalibrate the participant's measure scores to a denominator of 50

[29] MIPS benchmarks are published annually at https://qpp.cms.gov/about/resource-library.

points.[30] When a participant does not have sufficient cases for a given measure, the measure would be excluded from the AQS denominator calculation and the denominator would be recalibrated to reach a denominator of 50 points.

As discussed in the proposed rule, if a participant has sufficient cases to report data on three measures, it has a total of 30 possible points for the quality measure component. If the participant received a total of 20 out of 30 possible points on these measures the quality measure component score is 33.33 points after recalibrating the denominator to 50 points ((20/30) * 50 = 33.33). If a participant failed to report a measure, it would receive 0 out of 10 points for the measure and the participant would have a total of 40 possible points for the quality measure component. If a participant scored 20 points out of 40 possible points, the quality measure component score would be 25 points after recalibrating the denominator to 50 points ((20/40) * 50 = 25).

For the submission of reporting clinical data, CMS proposes that Professional and Dual participants would either be considered "successful" reporters and receive full credit full credit for meeting the requirements, or "not successful" reporters and not receive any credit. CMS proposes to define successful reporting as the submission of clinical data for RO beneficiaries with any of the five proposed clinical diagnosis (cancer, prostate, breast, lung, bone metastases, and brain metastases). If the participant does not successfully report sufficient data to meet the 95 percent threshold, it would receive 0 out of 40 points for the clinical data element component.

To calculate the AQS, CMS proposes to sum each participant's points awarded for clinical data reporting with its aggregated points award for quality measures to obtain a value that ranges between 0 to 100 points. The AQS would be divided by 100 points to express the AQS as a percentage.

CMS provides two examples for calculation of the AQS. Table 8, reproduced below, provides the AQS calculation for a Professional or Dual participant that did not meet the minimum case requirements for one of the pay-for-performance measures. Table 9 provides the AQS calculation for a participant that did not meet the reporting requirements for the clinical data elements and the pay-for reporting quality measure.

Table 8: Example of AQS Calculation

	Notes	Participant Score	Maximum Points	Formula
Quality Measures				
Measure 1 (a)	Pay-for-performance	10	10	
Measure 2 (b)	Pay-for-performance	3	10	
Measure 3 (c)	Pay-for-performance	0	0	

[30] The CAHPS Cancer Care Survey for Radiation Therapy would be added into the AQS beginning in PY3 and CMS will propose the specific weights of selected measures from the CAHPS survey in future rulemaking.

Table 8: Example of AQS Calculation				
	Notes	**Participant Score**	**Maximum Points**	**Formula**
	In this example, the measure did not meet the minimum case requirements.			
Measure 4 (d)	Pay-for-reporting	10	10	
Subtotal (e)		23	30	e = a+b+c+d
Weighted to 50% (f)		38.3	50	f = (participant score of e * 50)/maximum points of e
Clinical Data Elements (g)	≥95% of applicable RO beneficiaries	50	50	
Total		88.3	100	h = f+g
AQS (i)		88.3%		I = participant score of h/maximum points of h

CMS proposes to continue to weight measures equally in PY 1 through PY5. Any updates would be proposed and finalized through rulemaking.

Proposal to Apply the AQS to the Quality Withhold

CMS proposes to multiply the Professional of Dual participant's AQS (as a percentage) against the 2 percent quality withhold amount. For example, if a participant received an AQS of 88.3 out of a possible 100, the participant would receive a 1.77 percent quality reconciliation payment amount (0.883 * 2.0 = 1.77%). Using the information in Table 5, line (j) of the proposed rule, the payment amount for this RO participant, after applying the trend factor, adjustments, and discount factor is $2,6465.68. An AQS of 88.3 results in a quality reconciliation quality amount of $42.64 ($2,465.68 8 1.77% = $43.64), prior to the geographic adjustment and sequestration.

The AQS will be calculated approximately eight months after the end of each PY and applied to calculate the quality withhold payment amount for the relevant PY. Any portion of the quality withhold that is earned back would be distributed in the annual lump sum during the reconciliation process.

9. The RO Model as an Advanced APM and a MIPS APM

CMS anticipates that the proposed RO Model would meet the criteria necessary for an Advanced APM and a MIPS APM in the Quality Payment Program (QPP). The RO participant, specifically either a Dual participant or a Professional participant, would be the APM Entity, under its proposal.

CMS proposes to establish an "individual practitioner list" under the RO Model (§512.205). This would be created by CMS and sent to Dual participants and Professional participants to review, revise, certify, and return to CMS so that it may make Qualifying APM Participants (QP) determinations for the APM incentive payment amount and to identify any MIPS eligible clinicians who would be scored for MIPS based on their participation in this MIPS APM. If

finalized as proposed, the individual practitioner list would serve as the Participation List in the QPP. The list would include physician radiation oncologists that are eligible clinicians participating in the RO Model with either a Dual participant or Professional participant. Only Professional participant physicians and Dual participant physicians included on the individual practitioner list would be considered eligible clinicians. CMS notes that it is not proposing that HOPDs that are Technical participants be a part of this list process because as HOPDs, they are paid by OPPS, which is not subject to the QPP.

CMS proposes several other requirements related to the individual practitioner list. It proposes that prior to the start of each PY, it would create and provide each Dual participant and Professional participant with an individual practitioner list. Participants must review and certify the individual participant list within 30 days of receipt of such list in a form and manner specified by CMS. For those participants that begin the RO model after the start of the PY, but at least 30 days prior to the final QP snapshot date of that PY, CMS would create and provide the new Dual participant or Professional participant with an individual practitioner list. In order to certify the list, CMS reiterates the requirement that an individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the list.

CMS also proposes that RO participants may make changes (i.e., additions or removals) to the individual practitioner list that has been certified at the beginning of the performance year. In order to make additions to the list, the RO participant must notify CMS within 15 days of an individual practitioner becoming a Medicare-enrolled supplier that bills for RT services under a billing number assigned to the TIN of the RO participant; the timely addition will be effective on the date specified in the notice furnished to CMS, but not earlier than 15 days before the date of the notice. If the RO participant fails to submit timely notice of the addition, the addition is effective on the date of the notice. CMS would determine the form and manner of the notice. A similar process and timeline would apply for removal of an individual practitioner from the list.

CMS further proposes that if the Dual participant or Professional participant does not verify and certify the individual practitioner list by the deadline specified by CMS, then the unverified list would be used for scoring under MIPS using the APM scoring standard. It proposes to codify these provisions at §512.217.

To qualify as an Advanced APM, the RO Model must meet certain criteria specified in regulation at 42 CFR 414.1415.

First, an APM must require participants to use certified EHR technology (CEHRT). Specifically, for QP Performance Periods beginning in 2019 an Advanced APM must require at least 75 percent of eligible clinicians in the APM Entity or, for APMs in which hospitals are the APM Entities, each hospital, to use CEHRT to document and communicate clinical care to their patients or other health care providers. CMS proposes that during the model performance period, the RO participant would be required to annually certify its intent to use CEHRT throughout such model year. Annual certification would be required prior to the start of each subsequent PY.

Second, an APM must include quality measure performance as a factor when determining payment to participants for covered professional services under the terms of the APM. Effective January 1, 2020, at least one of the quality measures upon which the APM bases payment must meet at least one of the following criteria: (a) finalized on the MIPS final list of measures, as described in 42 CFR 414.1330; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidence-based, reliable, and valid. CMS believes its proposed quality measures (discussed in section III.C.8.b.) would meet the quality criteria. Regulations under 42 CFR 414.1415(b) (3) also specifies that an Advanced APM base payment must include at least one outcome measure. CMS states, however, that this requirement does not apply if there are no available or applicable outcome measures included in the MIPS quality measures list for the APM's first QP Performance Period. CMS states here currently are no such outcome measures available or applicable, but will reexamine this issue in the future.

Third, the APM must require participating APM Entities to bear financial risk for monetary losses of more than a nominal amount or, be a Medical Home Model expanded under the Innovation Center's authority, in accordance with section 1115A(c) of the Act. CMS expects that the RO Model would meet the generally applicable financial risk standard because there is no minimum (or maximum) financial stop loss for RO participants, meaning RO participants would be at risk for all of the RT services beyond the episode payment amount. CMS states that the RO Model meets other requirements because CMS would not pay the RO participant more for RT services than the episode payment amount. The APM Entity is also responsible for actual expenditures that exceed expected expenditures – the RO participate is responsible for 100 percent of those costs without any stop-loss or cap on potential losses for RT services furnished during the 90-day episode.

Additionally, CMS anticipates that the proposed RO Model would meet the criteria to be a MIPS APM under the Quality Payment Program starting in PY1. Pursuant to §414.1370(a), MIPS eligible clinicians who are identified on a participation list for the performance period of an APM Entity participating in a MIPS APM are scored under MIPS using the APM scoring standard. CMS proposes to use the same individual practitioner list developed as previously proposed, to identify the relevant eligible clinicians for purposes of making QP determinations and applying the APM scoring standard under the Quality Payment Program.

CMS notes that the following proposals would apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

- Its proposals regarding monitoring, audits and record retention, and remedial action, as described in section II.F and III.C.14. Under its proposed monitoring policy, RO participants would be monitored for compliance with the RO Model requirements. CMS may, based on the results of such monitoring, deny an eligible clinician who is participating in the RO Model QP status if the eligible clinician or the eligible clinician's APM entity (that is, the respective RO participant) is non-compliant with RO Model requirements.

- Its proposal in section III.C.10.c, which explains that technical component payments under the RO Model would not be included in the aggregate payment amount for covered professional services that is used to calculate the amount of the APM Incentive Payment.

CMS invites comment on these proposals.

10. Proposed Medicare Program Waivers

CMS proposes to waive certain requirements of title XVIII of the Act solely for purposes of carrying out testing of the RO Model under section 1115a (b) of the Act. CMS cites its goal of ensuring site-neutral payments as a reason for many of these proposed waivers. These proposed waivers include the following:

- Proposes to waive the Hospital Outpatient Quality Reporting (OQR) Program payment reduction authorized under section 1833(t)(17)(A) of the Act. CMS would not apply the two-percentage point reduction to their outpatient department fee schedule increase factor for APCs that contain RO-Model-specific HCPCS codes. APCs not included in the model would still be subject to the 2.0 percentage point reduction under the Hospital OQR Program, when applicable.

- Proposes to waive the requirement to apply the MIPS payment adjustment factors under section 1848(q)6)(E) of the Act and 42 CFR 414.1405(e) that may otherwise apply to payment for services billed under the professional RO Model-specific HCPCS codes. CMS states that the MIPS payment adjustment factors are determined in part based on MIPS eligible clinician's performance on quality measures for a performance. Subjecting a RO participant to payment consequences under MIPS and the Model for potentially the same quality measures could have unintended consequences.

- Proposes to waive requirements to include TC payments in calculation of the APM Incentive Payment amount. The APM Incentive Payment amount for an eligible clinician who is a QP is equal to 5 percent of his/her prior year estimated aggregate payments for covered professional services. CMS is concerned that without this waiver Dual participants may change their billing behavior by shifting the setting in which they furnish RT services from HOPDs to freestanding radiation therapy centers in order to increase the amount of participant-specific episode payments, and produce unwarranted increases in their APM Incentive Payment amount.

In addition, CMS proposes waiving certain general payment requirements with regard to how payments are made in order to allow the RO Model's prospective episode payment to be fully tested. CMS propose to waive:

- Section 1848(a)(1) of the Act that requires payment for physicians' services to be determined under the PFS to allow the PC and TC payments for RT services to be made as set forth in the RO Model.
- Section 1833(t)(1)(A) of the Act that requires payment for outpatient department (OPD) services to be determined under the OPPS to allow the payments for TC services to be

paid as set forth in the RO Model (waiver of OPPS payment would be limited to RT services under the RO Model); and

- Section 1833(t)(16)(D) of the Act regarding payment for stereotactic radiosurgery to allow the payments for TC services to be paid as set forth in the RO Model.

CMS proposes to waive section 1869 of the Act specific to claims appeals to the extent otherwise applicable. It proposes to implement this waiver so that RO participants may utilize the proposed timely error and reconsideration request process specific to the RO Model to review potential RO Model reconciliation errors (as proposed in section III.C.12 of this proposed rule). CMS notes that if RO participants have general Medicare claims issues, then the RO participants should continue to use the standard CMS claims appeals procedures. CMS also stresses that its proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869.

CMS also believes it is necessary for testing the RO Model to waive application of the PFS relativity adjuster which applies to payments under the PFS for "non-excepted" items and services.[31] This applies to nonexcepted off-campus provider based departments (PBDs); the PFS relativity adjusted is currently set at 40 percent of the OPPS rate. Under the RO Model, CMS proposes to waive requirements for all RO Model-specific payments to applicable OPDs. If a nonexcepted off-campus PBD were to participate in the RO Model, it would be required to submit RO Model claims consistent with CMS professional and technical billing proposals. CMS would not apply the PFS relativity adjusted to the RO Model payment and instead would pay them in the same manner as other RO Model participants. CMS believes this waiver is necessary to allow for consistent model evaluation and ensure site neutrality in RO Model payments, which is a key feature of the RO Model.

CMS invites comments on its proposed payment waivers.

11. Proposed Reconciliation Process

CMS proposes to conduct an annual reconciliation for each RO participant after each PY to reconcile payments due to the RO participant with payments owed to CMS due to the withhold policies. The annual reconciliation would occur in August following a PY in order to allow time for claims run-out, data collection, reporting, and calculating results. For example, the annual reconciliation for PY1 would occur in August of 2021.

a. Proposed True-Up Process

CMS also proposes to conduct an annual true-up of reconciliation for each PY, which would mean the process to calculate additional payments or repayments for incomplete episodes and duplicate RT services that are identified after claims run-out. CMS, for example, would true-up the PY1 reconciliation approximately one year after the initial reconciliation results were calculated. As a result, CMS would conduct a true-up of PY1 in August 2022, a true-up of PY2 in August 2023, and so forth.

CMS invites comments on its proposed true-up process.

[31] Identified by Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74), which amended section 1833(t)(1)(B)(v) of the Act and added paragraph (t)(21) to the Social Security Act.

b. Proposed Reconciliation Amount Calculation

To calculate a reconciliation payment amount either owed to a RO participant by CMS or a reconciliation repayment amount owed by CMS to a RO participant, CMS proposes the following process:

To calculate the incorrect payment reconciliation amount CMS would:

> Sum all money the RO participant owes CMS due to incomplete episodes and duplicate services, and subtract the amount from the incorrect payment withhold amount (that is, the cumulative withhold of 2 percent on episode payment amounts for all episodes furnished during that PY by that RO participant).

This would determine the amount owed to CMS by the RO participant based on total payments made to the RO participant for incomplete episodes and duplicate RT services for a given PY, if applicable. A RO participant would receive the full incorrect payment withhold amount if it had no duplicate RT services or incomplete episodes (as explained in section III.C.6.g). In instances where there are duplicate RT services or incomplete episodes, the RO participant would owe a repayment amount to CMS if the amount of all duplicate RT services and incomplete episodes exceeds the incorrect payment withhold amount.

CMS provides additional detail in the proposed rule for Professional, Technical, and Dual participants. Table 10 in the proposed rule (reproduced here) represents an illustrative example reconciliation for a Professional participant. In this example, a total payment of $6,600 total reconciliation payment (c) is due to the participant from CMS for that PY after withhold adjustments. CMS notes that this example does not include the geographic adjustment or the 2 percent adjustment for sequestration.

Table 10: Example Reconciliation Calculation for a Professional Participant

Professional participant	**Formula**	**Example 1**
Incorrect Payment Reconciliation Amount (a)		
Incorrect Payment Withhold Amount (a_1)	a_1	$6,000
Duplicate RT Services Adjustment (a_2)	a_2	($3,000)
Incomplete Billing Adjustment (a_3)	a_4	($1,500)
Total ($a_1 + a_2 + a_3$)	$a = a_1 + a_2 + a_3$	$1500
Quality Reconciliation Amount (b)		
Quality Withhold (b_1)	b_1	$6,000
AQS (b_2)	b_2	0.85
Product ($b_1 * b_2$)	$b = b_1 * b_2$	$5,100
Total Payment/Recoupment (c)	c = a + b	$6,600

CMS invites comment on its proposal on calculating reconciliation amounts.

12. Proposed Timely Error Notice and Reconsideration Request Processes

CMS proposes a policy that would permit RO participants to contest errors found in the RO reconciliation report, but not the RO Model pricing methodology or AQS methodology. CMS notes that, if RO participants have Medicare FFS claims or decisions they wish to appeal outside of the scope of the RO Model, then the RO participants should continue to use the standard CMS procedures through their MACs.

CMS proposes to waive the requirements of section 1869 of the Act specific to claims appeals as necessary solely for purposes of testing the RO Model. CMS believes it is necessary to establish different appeal process for RO participants to dispute suspected errors in the calculation of their reconciliation payment amount, repayment amount, or AQS. It believes that such a process will lead to more timely resolution of disputes.

CMS proposes a two-level process consistent with processes the Innovation Center has implemented under other models. The first level would be a timely error notice process and the second level would be a reconsideration review process. Only RO participants may utilize either the first or second level of the reconsideration process.

a. Timely Error Notice

Building off of its experiences with other models, CMS proposes that the first level of the proposed reconsideration process would be a timely error notice. Specifically, CMS proposes that RO participants could provide written notice to CMS of a suspected error in the calculation of their reconciliation payment amount, repayment amount, or AQS for which a determination has not yet been deemed to be final. The RO participant would have 30 days from the date the RO reconciliation report is issued to provide their timely error notice. CMS notes that this would be subject to the limitations on administrative and judicial review.

CMS proposes that the written notice must be submitted in a form and manner specified by CMS. Unless the RO participant provides such notice, the RO participant's reconciliation payment amount, repayment amount, or AQS would be deemed final after 30 days, and CMS would proceed with payment or repayment, as applicable. If CMS receives a timely notice of an error, CMS proposes that it would respond in writing within 30 days to either confirm that there was a calculation error or to verify that the calculation is correct. CMS reserves the right to an extension upon written notice to the RO participant. It proposes to codify this timely error notice policy at §512.290(a).

b. Reconsideration Review

CMS proposes that the second level of the proposed reconsideration process would permit RO participants to dispute CMS's response to the RO participant's identification of errors in the timely error notice, by requesting a reconsideration review by a CMS reconsideration official. The CMS reconsideration official would be a designee of CMS who is authorized to receive such requests and who was not involved in the responding to the RO participant's timely error notice. CMS proposes that for a request to be considered, the reconsideration review request must be submitted to CMS (in a form and manner specified by CMS) within 10 days of the issue date of CMS' written response to the timely error notice. CMS proposes that to access the

reconsideration review process, a RO participant must have timely submitted a timely error notice to CMS in the form and manner specified by CMS, and this timely error notice must not have been precluded from administrative and judicial review. Otherwise, this process would not be available to the RO participant.

For those RO participants that submitted a timely error notice, CMS proposes that the reconsideration review request must provide a detailed explanation of the basis for the dispute and include supporting documentation for the RO participant's assertion that CMS or its representatives did not accurately calculate the reconciliation payment amount, repayment, recoupment amount, or AQS in accordance with the terms of the RO Model. This process would be an on-the-record review (a review of the memoranda or briefs and evidence only) conducted by a CMS reconsideration official. CMS states that the CMS reconsideration official would make reasonable efforts to notify the RO participant and CMS in writing within 15 days of receiving the RO participant's reconsideration review request of the following: the issues in dispute, the briefing schedule, and the review procedures.

The briefing schedule and review procedures would lay out the timing for the RO participant and CMS to submit their position papers and any other documents in support of their position papers; the review procedures would lay out the procedures the reconsideration official will utilize when reviewing the reconsideration review request. The CMS reconsideration official would make all reasonable efforts to complete the on-the-record review of all the documents submitted by the RO participant and issue a written determination within 60 days after the submission of the final position paper in accordance with the reconsideration official's briefing schedule. CMS proposes that the determination made by the CMS reconsideration official would be final and binding. This proposes process would be codified at §512.290(b).

CMS seeks comment on its proposed provisions regarding the proposed timely error notice and reconsideration review processes.

13. Proposed Data Sharing

Based on the design elements of each model, CMS may offer participants the opportunity to request different types of data to help them improve quality and coordinated care for model beneficiaries. As described above (section 8. Quality), in order to evaluate and monitor the proposed model, CMS may require model participants to report certain data. The proposed requirements for data related requirements are described below.

a. Data Privacy Compliance

As a condition of receipt of patient-identifiable data from CMS for purposes of the RO model, RO participants must comply with all applicable laws pertaining to any patient-identifiable data requested from CMS under the terms of the RO Model and the terms of any agreement entered into by the RO participant and CMS as a condition of the RO participant receiving such data.

These laws include, without limitation, the privacy and security standards under the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 (HIPPA) and the Health Infusion Technology for Economic and Clinical Health Act (HITECH).

CMS believes requiring RO participants to bind their downstream recipients in writing to comply with appropriate laws and requirements is necessary to protect the individually identifiable health information data that may be shared with RO participants by CMS for care redesign and care coordination purposes. CMS proposes that RO participants would be required to contractually bind all downstream recipients of CMS data to comply with all laws pertaining to any patient-identifiable data requested from CMS and the terms of any agreement that the RO participant enters with CMS as a condition of receiving the data under the RO model, including maintenance of the data.

b. RO Participant Release of Patient De-Identified Information

CMS does not propose to restrict RO participants' ability to publicly release de-identified information that references the RO participant's participation in the RO Model. Information that may be publicly released may include, but is not limited to, press releases, journal articles, research articles, external reports that have been de-identified in accordance with HIPPA requirements in 45 CFR 164.514(b).

CMS proposes to require the RO participant to include a disclaimer on the first page of any publicly released document whose content materially and substantially references or relies upon the RO participant's participation in the RO Model. Specifically, CMS proposes the same disclaimer that it proposes for purposes of descriptive model materials and activities:

> "The statements contained in this document are solely those of the authors and do not necessarily reflect the views of policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

CMS believes this disclaimer is necessary so the public, including RO beneficiaries, are not misled into concluding that RO participants are speaking on behalf of the agency.

c. Proposed Data Submitted by RO Participants

CMS proposes that RO participants supply and or confirm a limited amount of summary information to CMS including:

- the RO participant's TIN for a freestanding radiation therapy center and physician group practice, or CCN for a HOPD;
- providing and/or confirming the NPIs for physicians who bill RT service using the applicable TINs; and
- information on the number of Medicare and non-Medicare patients treated with radiation during their participation in the Model.

CMS also proposes to require RO participant's submission of additional administrative data upon request from CMS, such as the cost to provide care (e.g. the acquisition cost of a linear accelerator) and how frequently the radiation machine is used on an average day; current EHR vendors; and accreditation status.

CMS proposes to obtain this information through annual web-based surveys. CMS states the information will be used to understand participants' office activities, benchmarks, and track participant compliance.

d. Proposed Data Provided to RO Participants

Thirty days prior to the start of each PY, CMS proposes to provide RO participants with updated participant-specific professional episode payment and technical episode payment amounts (e.g. episode price files) for each included cancer type. CMS states that RO participants (to the extent allowed by HIPAA and other applicable laws) could also reuse individually identifiable claims data they requested from CMS for quality improvements in their assessment of CMS' calculations of their participant-specific episode payment amount and in amounts included in the reconciliation calculations. To request data from CMS, RO participants will use a Participant Data Request and Attestation (DRA) form, which will be available on the RO Model website. If RO participants continue to use data for quality improvement and care coordination, participants may request to continue to receive this data until the final reconciliation and final true-up process has been completed. As the conclusion of the model, the participant would be required to maintain or destroy all data in accordance with the DRA and applicable law.

CMS proposes that the RO participant may reuse original or derivative data without prior written authorization from CMS for clinical treatment, care management, quality improvement activities, and provider incentive design and implementation. The original or derivative data cannot be disseminated to the following:

- anyone who is not a HIPAA Covered Entity Participant or individual practitioner in a treatment relationship with the subject Model beneficiary;
- a HIPAA Business Associate of such a Covered Entity or individual practitioner;
- the participant's business associate, where that participant is itself a HIPAA Covered Entity;
- the participant's sub-business associate, which is hired by the RO participant to carry out work on behalf of the Covered Entity Participant or individual practitioners; or
- a non-participant HIPAA Covered Entity in a treatment relationship with the subject Model beneficiary.

CMS proposes that when using or disclosing protected health information (PHI) or personally identifiable information (PII) obtained from files specified in the DRA, the RO participant would be required to make "reasonable efforts to limit" the information to the "minimum necessary" to accomplish the intended purpose of the use, disclosure or request (45 CFR 164.500 through 164.534). The RO participant would be required to further limit disclosure of information to what is permitted by applicable laws, including HIPAA and HITECH, and disclosures that CMS would be permitted to make under the "routine uses" in the applicable systems of records notices listed in the DRA.

CMS proposes that the RO participant may link individually identifiable information specified in the DRA or derivative data to other sources of individually identifiable health information, such as other medical records. The RO participant would be authorized to disseminate data that has

been linked to other sources of individually identifiable health information as long as the data has been de-identified in accordance with HIPAA requirements.

e. Access to Share Beneficiary Identifiable Data

CMS states that the data and reports provided to the RO participant in response to a DRA would not include any beneficiary-level claims data regarding utilization of substance use disorder services. To obtain beneficiary-level substance use disorder information the requestor must provide a compliant authorization from each individual whom they seek such data. CMS states that the RO participants and its individual practitioners should consult their own counsel to make the determination that all the applicable HIPAA requirements for requesting data under 45 CFR 164.506(c)(4) are met.

Agreeing to the terms of the DRA, the RO participant, at a minimum, would agree to establish appropriate administrative, technical, and physical safeguards to protect confidentiality of the data and to prevent unauthorized use of or access to it. The safeguards would be required to provide a level of security that is no less than the requirements established for federal agencies by OMB[32], Federal Information Processing Standard 200[33], and NIST Special Publication 800-53[34].

CMS proposes the RO participant would be required to acknowledge that the use of unsecured telecommunications, including insufficiently secured transmissions over the Internet, to transmit directly or indirectly identifiable information from the files specified in the DRA or any such derivative data files would be strictly prohibited. In addition, the RO participant would be required to agree that the data specified in the DRA would not be physically moved, transmitted, or disclosed in any way from or by the site of the Data Custodian indicated in the DRA without written approval from CMS, unless such movement, transmission, or disclosure is required by law. At the conclusion of the RO Model and reconciliation process, the RO participant would be required to destroy all data in its possession as agreed upon under the DRA.

14. Proposed Monitoring

CMS notes that, if finalized, the general provisions relating to monitoring and compliance proposed in section II.I of this rule would apply to the RO Model. RO participants would need to cooperate with model monitoring and evaluation activities in accordance with §512.135(a), §§512.135(b) and (c), and §512.150(b). CMS believes these general provisions relating to monitoring and compliance are appropriate for the RO Model and helps ensure that the model is implemented safely and appropriately;

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[32] This information is in OMB Circular No.A-130, Appendix I- Responsibilities for Protecting and Managing Federal Information Resources and available at https://obamawhitehouse.archives.gov/sites/default/files/omb/assets/OMB/circulars/a130/a130revised.pdf.

[33] Federal Information Processing Standard 200 is titled "Minimum Security Requirements for Federal Information and Information Systems" and available at http://csrc.nist.gov/publications/fips/fips200/FIPS-200-final-march.pdf

[34] NIST Special Publication 800-53 is titled "Recommended Security Controls for Federal Information Systems" and available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf

Consistent with §512.150(b), CMS anticipates that monitoring activities may include documentation requests sent to RO participants and individual practitioners on the individual practitioner list; audits of claims data, quality measures, medical records, and other data from RO participants and clinicians on the individual practitioner list; interviews with members of the staff and leadership of the RO participant and clinicians on the individual practitioner list; interviews with beneficiaries and their caregivers; monitoring quality outcomes; site visits; monitoring quality outcomes and clinical data, if applicable; and tracking patient complaints and appeals. Monitoring could include tracking utilization of certain types of treatments, beneficiary hospitalization and emergency department use, and fractionation (numbers of treatments) against historical treatment patterns for each participant. Additionally, CMS may employ longer-term analytic strategies to confirm its ongoing analyses and could include, for example, pairing clinical data with claims data to identify specific issues by cancer type.

a. Proposed Monitoring for Utilization/Costs and Quality of Care

CMS states that it will monitor RO participants for compliance with RO Model requirements. This includes monitoring to detect possible attempts to manipulate the system through patient recruitment and billing practices. CMS anticipates monitoring compliance with RO Model-specific billing guidelines and adherence to current LCDs which provide information about the only reasonable and necessary conditions of coverage allowed. CMS also states it intends to monitor patient and provider/supplier characteristics, such as variations in size, profit status, and episode utilization patterns, over time to detect changes that might suggest attempts at such manipulation.

To allow CMS to conduct this monitoring, it states that RO participants would report data on program activities and beneficiaries consistent with the data collection policies proposed in section III.C.8. These data would be analyzed by CMS or its designee for quality, consistency, and completeness. Further information on this requirement would be provided to RO participants prior to data collection. CMS would also use existing authority to audit claims and services, to use the QIO to assess for quality issues, to use its authority to investigate allegations of patient harm, and to monitor the impact of the RO Model quality metrics.

b. Proposed Monitoring for Model Compliance

CMS details the activities it will monitor for model compliance. This will include requiring all participants to annually attest that they would use CEHRT in a manner sufficient to meet the requirements. CMS also proposes that that each Technical participant and Dual participant would be required to attest annually that it actively participates in a radiation oncology-specific AHRQ-listed patient safety organization (PSO). CMS proposes to codify these RO Model requirements at §512.220(a)(3). CMS states that it may monitor the accuracy of such attestations and that false attestations would be punishable under applicable federal law.

In addition, CMS would monitor for compliance with the other RO Model requirements listed in this section through site visits and medical record audits conducted in accordance with §512.150.

Specifically, CMS proposes to codify at §512.220(a)(2) requiring all Professional participants and Dual participants document in the medical record that the participant:

(i) has discussed goals of care with each RO beneficiary before initiating treatment and communicated to the RO beneficiary whether the treatment intent is curative or palliative;
(ii) adheres to nationally recognized, evidence-based clinical treatment guidelines when appropriate in treating RO beneficiaries or document in the medical record the rationale for the departure from these guidelines;
(iii) assesses the RO beneficiaries' tumor, node, and metastasis (TNM) cancer stage for the CMS-specified cancer diagnoses;
(iv) assesses the RO beneficiary's performance status as a quantitative measure determined by the physician;
(v) sends a treatment summary to each RO beneficiary's referring physician within three months of the end of treatment to coordinate care;
(vi) discusses with each RO beneficiary prior to treatment delivery his or her inclusion in, and cost-sharing responsibilities under, the RO Model; and
(vii) performs and documents 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.

c. Proposed Performance Feedback

CMS proposes to provide detailed and actionable information regarding RO participant performance related to the RO Model. Such information could include RO participants' adherence to evidence-based practice guidelines, quality and patient experience measures, and other quality initiatives. CMS states that the design of and frequency that these reports provided to participants would be determined in conjunction with the RO Model implementation and monitoring contractor.

d. Proposed Remedial Action for Non-Compliance

CMS refers readers to section II.J of this proposed rule and summary for its proposals regarding remedial and administrative action.

CMS invites comment on its monitoring proposals.

15. Beneficiary Protections

CMS proposes to require that Professional participants and Dual participants notify RO beneficiaries that it is participating in this RO Model by providing written notice during the RO beneficiary's initial treatment planning session. CMS states that it intends to provide a notification template that RO participants may personalize with their contact information and logo. This template would include language explaining that the RO participant is participating in

the RO Model, information regarding RO beneficiary cost-sharing responsibilities and a RO beneficiary's right to refuse having his or her data shared under §512.225(a)(2). If the RO participant refuses to share its information, the RO participant must provide written notice to CMS within 30 days of when the beneficiary notifies the RO participant.

CMS believes that providing a standardized, CMS-developed RO beneficiary notice would limit the potential for fraud and abuse, including patient steering. Given that CMS is providing the standardized language, it proposes that the required RO Model beneficiary notice be exempt from the requirement at §512.120(c)(2) and in section II.D.3 of this part, which requires that the model participant include the standard disclaimer statement on all descriptive model materials and activities CMS proposes these policies at §512.225(c).

Beneficiaries with any questions or concern with their physicians are encouraged to contact CMS using the 1–800–MEDICARE, or their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs).

CMS invites comment on the proposed beneficiary protections.

16. Proposed Evaluation

Under section 1115A(b)(4) of the Act, the Secretary is required to evaluate each model tested by the Innovation Center. An evaluation of the RO Model would be required to be conducted in accordance with which requires the Secretary to evaluate each model tested by the Innovation Center.

CMS states that its evaluation of the RO Model would focus primarily on understanding how successful the RO Model is in achieving improved quality and reduced expenditures. The evaluation would include, for example, evidence of changes in RT utilization patterns (including the number of fractions and types of RT); RT costs for Medicare FFS beneficiaries in the RO Model (including Medicare-Medicaid dually eligible beneficiaries); changes in utilization and costs with other services that may be affected as a result of the RO Model (such as emergency department services, imaging, prescription drugs, and inpatient hospital care); performance on clinical care process measures (such as adhering to evidence-based guidelines); patient experience of care; and provider experience of care. CMS believes that the evaluation would inform the Secretary and policymakers about the impact of the model relative to the current Medicare fee structure for RT services and assess the impacts on beneficiaries, providers, markets, and the Medicare program.

CMS describes a number of questions the evaluation may include to help address, including, but not limited to the following:

- Did utilization patterns with respect to modality or number of fractions per episode change under the model?
- If the model results in lower Medicare expenditures, what aspects of the model reduced spending and were those changes different across subgroups of beneficiaries or related to observable geographic or socio-economic factors?

- Did any observed differences in concordance with evidence-based guidelines vary by cancer type or by treatment modality?
- Did patient experience of care improve?
- Did the model affect access to RT or other services overall or for vulnerable populations?
- Were there design and implementation issues with the RO Model?
- What changes did participating radiation oncologists and other RO care team members experience under the model?
- Did any unintended consequences of the model emerge?
- Was there any observable overlap between the RO Model and other CMMI models or
- CMS/non-CMS initiatives and how could they impact the evaluation findings?

CMS briefly describes the potential analytic approach it would use to estimate model effects. It anticipates using a difference-in-differences or similar analytic approach to estimate model effects. CMS will develop a multi-level dataset and analytic approach that examines relationships over time (pre and post the use of the RO Model) and at the CBSA-level, participant-level, and the beneficiary-level. The evaluation approach would control for patient differences and other factors that directly and indirectly affect the RO Model impact estimate, including demographics, comorbidities, program eligibility, and other factors. Data to control for patient differences would be obtained primarily from claims and patient surveys.

CMS invites comment on its proposed approach related to the evaluation of the RO Model.

17. Termination of the RO Model

CMS states that the proposed general provisions relating to termination of the Model by CMS proposed in section II.J of this rule would apply to the RO Model.

18. Potential Overlap with Other Models Tested under Section 1115A Authority and CMS Programs

a. Overview

CMS believes that the RO Model would be compatible with other CMS models and programs, but recognizes that overlap could exist with other models being tested by the Innovation Center. CMS does not currently envision that the prospective episode payments made under the RO Model would need to be adjusted to reflect payments made under any of the existing models being tested under section 1115A of the Act or the Medicare Shared Savings Program (Shared Savings Program) under section 1899 of the Act. CMS states that if such adjustments are necessary, it would propose overlap policies for the RO Model through notice and comment rulemaking.

b. Accountable Care Organizations (ACOs)

With respect to ACOs, CMS believe there would be potential overlap between the proposed RO Model and ACO initiatives. CMS believes, however, that because the RO Model is an episode-based payment initiative, providers and suppliers participating in the RO Model would not be precluded from also participating in an ACO initiative. Specifically, CMS believes overlap could likely occur in two instances: (1) the same provider or 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 at a radiation oncology provider or supplier outside the ACO that is participating in the RO Model.

CMS recognizes that while shared savings payments made under an ACO initiative have the potential to overlap with discounts and withholds in the RO Model, it is difficult to determine the level of potential overlap at this time. CMS states it intends to continue to review the potential overlap, and if substantial overlap occurs, it would consider adjusting the RO Model payments through future rulemaking to ensure Medicare retains the discount amount.

c. Oncology Care Model (OCM)

CMS anticipates that there would be beneficiaries who would be in both Oncology Care Model (OCM) episodes and the RO Model Episodes as both involve care for patients with a cancer diagnosis who receive RT services. As background, OCM episodes encompass a 6-month period that is triggered by the receipt of chemotherapy and incorporate all aspects of care during that timeframe, including RT services.

CMS makes the point that the RO Model is not a total cost of care model and only includes RT services in the episode payment. Since the RO Model makes prospective payments for only the RT services provided during an episode, a practice participating in the RO Model would receive the same prospective episode payment for RT services regardless of its participation in OCM.

OCM, however, is a total cost of care model so any changes in the cost of RT services during an OCM episode could affect OCM episode expenditures, and therefore, have the potential to affect a participating practice's performance-based payment (PBP) or recoupment.

In the event that an entire RO Model episode (90-days of RT services) occurs completely during a 6-month OCM episode, then the associated RO payments for RT services would be included in the OCM episode. In addition, to account for the savings generated by the RO Model discount and withhold amounts, CMS proposes that it would add the RO Model's discount and withhold amounts to the total cost of the OCM episode during OCM's reconciliation process to ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models.

In those cases where the RO Model episode would occur partially within an OCM episode and partially before or after the OCM episode, CMS proposes to allocate the RO Model payments for RT services and the RO Model discount and withhold amounts to the OCM episode on a prorated basis, based on the number of days of overlap. Including the prorated discount and

withhold amounts would ensure that there is no double counting of savings and no double payment of the withhold amounts between the two models. CMS assumes that all withholds are eventually paid to the RO Participant under the RO Model, and that there are no payments to recoup. CMS believes developing a process to allocate exact amounts paid to the participants with different reconciliation timelines between the two models would be operationally complex.

CMS states its intention to continue to review the potential overlap with OCM if the RO Model is finalized as proposed, including whether there are implications for OCM's prediction model for setting risk-adjusted target episode prices, which include receipt of RT services.

d. Bundled Payments for Care Improvement (BPCI) Advanced

BPCI Advanced is testing a new iteration of bundled payments for 37 clinical episodes (33 inpatient and 4 outpatient). BPCI Advanced is based on a total cost of care approach with certain MS-DRG exclusions. CMS notes that while there are no cancer episodes included in the design of BPCI Advanced, a beneficiary in a RO episode could be treated by a provider or supplier that is participating in one of the 37 clinical episodes included in BPCI Advanced. CMS would provide further information to BPCI Advanced participants through an amendment to their participation agreement to determine whether BPCI Advanced participants would need to account for RO Model overlap in its reconciliation calculations.

19. Decision Not to Include a Hardship Exemption

CMS is not proposing and does not believe that a hardship exemption for RO participants under the RO Model is necessary, since the model's pricing methodology gives significant weight to historical experience in determining the amounts for participant-specific professional episode payments and participant-specific technical episode payments. CMS states that it is not proposing such an exemption in this proposed rule, and will not include such an exemption in the final rule. It may examine this issue in future rulemaking based on comments received.

CMS states it welcomes public input on whether a possible hardship exemption for RO participants under the Model might be necessary or appropriate, and if so, how it might be designed and structured while still allowing CMS to test the Model.

IV. End-Stage Renal Disease Treatment Choices (ETC) Model[35]

A. Background

1. Renal Replacement Therapy: Options and Usage

Chronic kidney disease (CKD) ranges from Stage I (mild disease) to Stage V (kidney function becomes insufficient to sustain life for more than a short time, also known as ESRD).[36] ESRD patients are dependent upon renal replacement therapy for filtration of waste and excess water from their bodies. Currently available therapy options are:

- Hemodialysis (HD), in which an external, artificial filter (the HD machine) performs filtration;
- Peritoneal dialysis (PD), in which filtration occurs across an internal filter, the peritoneal membrane that lines the abdominal cavity; and
- Kidney transplantation, in which a new internal filter – in the form of a donated kidney – is placed surgically into the recipient.[37]

HD is performed several times per week in a dialysis facility ("in-center dialysis") or at home; vascular access is required (e.g., fistula, graft, catheter). PD is performed multiple times weekly and is performed almost exclusively at home, though can be done in a facility; a PD catheter is required. After successful kidney transplantation, maintenance dialysis is no longer required.

Data collected for 2016 show that HD use predominated among ESRD patients in the United States (63 percent), of whom 98 percent dialyzed in facilities and 2 percent at home. PD was performed by 7 percent of ESRD patients, and 30 percent had functioning kidney transplants.[38] CMS notes that although both HD and PD may be suitable for many patients, multiple factors influence patient selection of therapy option and dialysis site and may reflect poorly understood self-selection bias. Described factors include patient education before dialysis initiation, availability of social and care partner support, socioeconomic factors, and patient perceptions and preferences, and unmeasured self-selection bias.

2. Comparisons of Renal Replacement Therapies

CMS provides some treatment option comparisons compiled from various sources (e.g., research studies, government program reports). HD rates, especially for in-center dialysis, are much

[35] Because children are excluded from the ETC model, information specific to pediatric dialysis generally will not be provided or discussed in this summary section.
[36] CKD stages are assigned based on patient estimated glomerular filtration rate (eGFR), supplemented by other tests as needed.
[37] In this summary, kidney transplantation is used to mean both kidney-only and kidney-pancreas transplantations, unless otherwise noted.
[38] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities. https://www.usrds.org/2018/view/v2_01.aspx

higher in the U.S. than in other countries, and home dialysis is performed at far lower rates. PD and home HD are much less frequently presented as options to patients initiating maintenance dialysis. Increased clinician and patient education about dialysis options correlates with higher rates of home dialysis (HD and PD) selection. In-center HD typically is readily accessible while home dialysis infrastructure more often appears to be constrained, and marginal costs for a facility to add an HD patient generally are less than to provide support to an additional home dialysis patient. Home dialysis appears to reduce overall medical expenditures per patient, due at least in part to fewer hospitalizations, fewer infections, and perhaps lower operating costs. Patient survival is better for PD compared to HD, although the difference narrows over time. Home dialysis appears to improve patients' quality of life and independence. Home dialysis rates have declined since the inception of the Medicare ESRD benefit, although interest in home dialysis seems to be increasing among patients and nephrologists.

Kidney transplantation reduces mortality, cardiovascular event risk, and annual medical expenditures while improving quality of life compared to maintenance dialysis. U.S. kidney transplantation rates per 1,000 dialysis patients are lower than in many other countries. Transplantation rates are most dependent upon donor organ supply, and about 5 percent of patients who are waitlisted die each year before receiving transplants, about 12 deaths per day. Economics could also influence rates, as a patient with a functioning transplant no longer requires a dialysis facility and requires fewer physician services. CMS takes particular notice of the possibility of increasing organ supply through decreasing the discard rate of potentially viable donor kidneys.

B. The Medicare ESRD program

1. History

In 1972, Medicare Part A and Part B eligibility was extended to individuals with ESRD regardless of age. As noted by CMS, at that time over 40 percent of U.S. dialysis patients were on home HD. Section 1881 was added to Title XVIII of the Act in 1978, establishing specific payments for ESRD-related care, including self-care home dialysis support services furnished by a provider of services or renal dialysis facility, home dialysis supplies and equipment, and institutional dialysis services and supplies. Explicitly stated in section 1881(c)(6) is the Congressional intent that home dialysis and transplantation should be maximally utilized for suitable patients. Starting with 1983, payment to facilities furnishing outpatient maintenance dialysis was made primarily through the "composite rate", a bundled payment for routine costs, recurring ESRD-related drugs, laboratory tests, items and services generally applicable to all dialysis options.[39]

The composite rate did not distinguish between provision of services at home or in a facility but did differentiate payments for hospital-based from independent facilities. The comprehensive nature of the composite rate was eroded over time as ESRD-related care evolved and newly-covered treatments were excluded from the bundle and paid separately (e.g., new drugs). The

[39] Facilities may choose to support some or all dialysis options: in-center hemodialysis, home hemodialysis or home peritoneal dialysis. Home dialysis support typically includes supplies, equipment, and professional staff visits.

Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed the development and implementation of a prospective payment system (PPS) under which a single payment is made for renal dialysis services in lieu of any other payment. MIPPA also provided for a pay-for-performance program to start in 2012. The ESRD PPS was fully phased in beginning in 2014.

2. Current Medicare Coverage of and Payment for ESRD Services

a. Overview

The bulk of Medicare's ESRD-related coverage is delivered under Part B: dialysis services furnished by outpatient facilities (includes some supplies and medications); home dialysis services, support and equipment; and professional services during a kidney transplant. Inpatient dialysis for patients admitted to a hospital or SNF for special care, as well as inpatient services for covered kidney transplants, are covered under Part A. Care of kidney donors is provided through Parts A and B. Coverage under Part C has been limited, primarily available only to beneficiaries already enrolled in MA plans prior to their ESRD diagnoses. However, already-diagnosed ESRD beneficiaries may choose to enroll in MA plans beginning in 2021, as provided in the 21st Century Cures Act. Part D coverage includes renal dialysis drugs available only in oral formulations.

b. ESRD PPS under Medicare Part B

A single dialysis treatment serves as the unit of payment under the ESRD PPS and assumes three treatments are provided each week. The base payment does not vary by dialysis type for adults (18 or more years of age), despite differences in equipment, supplies, labor, and dialysis frequency between HD and PD. The base payment is the same for dialysis whether performed at home or in a facility. The base rate is subject to several adjustments at the patient-level (case mix variables) and the facility-level (wage-index, low-volume, rural). Additions are made to the base payment when applicable for high-cost outlier beneficiaries, self-dialysis (home) training, and transitional drugs.[40] PPS payments are updated annually through the ESRD market basket and subject to a productivity adjustment. Under the ESRD Quality Incentive Program (QIP), facility payments also may be reduced by up to two percent when a facility fails to meet achievement and/or improvement targets on specified quality measures.

c. Monthly Capitation Payment (MCP)

Beneficiaries undergoing outpatient maintenance dialysis, whether at home or in a facility, generally receive several routine, recurring, ESRD-related services from a physician (e.g., establishing and adjusting the dialyzing cycle). Payment for these services is made directly by Medicare to a billing physician or qualified non-physician practitioner as a single monthly capitated payment, termed the MCP. The practitioner furnishing the services bundled into the MCP submits a claim using a set of age-specific CPT ESRD codes (90951-90970) that are

[40] The transitional drug add-on payment adjustment (TDAPA) allows separate payment for new injectable or intravenous products until sufficient data is collected to incorporate the product into the base payment.

distinct from CPT Evaluation/Management service codes. The number of visits per month also is specified in the CPT ESRD codes. The MCP varies with number of physician visits per month for in-facility dialysis but does not change with visit number for in-home dialysis.

d. Kidney Disease Education (KDE) Benefit

The KDE benefit was added under Part B by MIPPA for beneficiaries with Stage IV CKD beginning in 2010. Included are six 1-hour sessions that span a specified list of topics that includes choice of ESRD treatment furnished by a physician, physician assistant, nurse practitioner, or clinical nurse specialist (§410.48). One session must include performing an outcome assessment of how well the beneficiary is prepared to make informed treatment decisions. Utilization of the KDE benefit has been extremely low, under two percent of eligible beneficiaries. An analysis performed by the GAO cited the statutory restriction to Stage IV beneficiaries and limit on provider types furnishing the sessions as barriers to KDE uptake.[41]

4. Interaction between Medicare Payments and Dialysis Modality Choices

CMS notes several potential links (other than the proposed ETC model) between Medicare ESRD payments and dialysis modality choices that could impact home dialysis or transplantation utilization rates.

- Marginal costs per patient for increasing dialysis capacity are lower for in-center HD than for home dialysis.
- Care management of home dialysis patients may be more inefficient for clinicians than in-center HD patients. The physician can see multiple patients in a single dialysis facility, and home visits tend to be longer and more comprehensive.
- Separate payment is made to clinicians when a home dialysis patient completes a course of self-dialysis training (CPT code 90989; 90993 when the course is not completed).
- An add-on payment to the facility base payment is made when the facility furnishes self-dialysis training sessions (maximum of 15 sessions for PD and 25 sessions for HD).
- The first-year results of the Innovation Center's Comprehensive ESRD Care (CEC) Model, a total cost of care APM, did not show increased home dialysis utilization, suggesting participants did not focus on increasing home dialysis usage to increase quality or reduce expenditures.
- Beginning with performance year 2022, facilities will be scored on a new ESRD QIP measure, Percentage of Prevalent Patients Waitlisted (PPPW).
- CMS has proposed removing the Conditions of Participation requirement for outcomes data submission by transplant centers when seeking re-approval by Medicare; if finalized this reduced scrutiny could encourage use of potentially viable kidneys now being discarded so as not to reduce success rates.

[41] Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO-16-125, Oct 15, 2015). https://www.gao.gov/products/GAO-16-125

Coincident with announcing the ETC Model, CMS also announced several voluntary total cost of care APMs for CKD to begin in 2020 that provide financial incentives for successful transplants (e.g., Com

C. Policy Details of the Proposed ETC Model

1. Implementation Basics (§512.320)

Having reviewed U.S. renal replacement therapy usage patterns and outcomes for each treatment option, CMS concludes that evidence exists to support increased quality and decreased expenditures for the treatment of ESRD by kidney transplantation and home dialysis compared to in-center hemodialysis. CMS states that the ETC model is designed to test whether adjusting Medicare payments to dialysis facilities and clinicians treating beneficiaries with ESRD would increase the rates of home hemodialysis and kidney transplantation, thereby enhancing quality of care furnished to beneficiaries while reducing Medicare program costs. The mandatory model would provide for two payment adjustments, the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA), as well introduce additional flexibility in delivery of the Kidney Disease Education (KDE) benefit.

CMS proposes that the HDPA and PPA would be applicable both to dialysis facilities, through the ESRD PPS, and to clinicians who bill the monthly capitation payment (MCP) for managing ESRD beneficiaries, through the PFS. The model would be tested in randomly selected geographic areas that account for roughly half of Medicare's ESRD adult beneficiaries beginning in 2020. Adjustments would be made to payments for claims with through dates of June 30, 2026. Adjustment amounts would be based upon the home dialysis and transplantation rates among beneficiaries attributed to participating ETC facilities and clinicians as compared to achievement and improvement benchmarks. HDPA amounts would be positive while PPA amounts could be positive or negative. The HDPA is available only for the first three model years (2000-2002) while the PDA is made over the entire duration of the model (final adjustments occur in 2026). Also during the model testing period, the pool of patients eligible to receive the DKE benefit and the pool of providers eligible to furnish DKE services would be expanded.

CMS proposes to begin the model test on January 1, 2020, but considered an alternative start date of April 1, 2020. In the latter case, all intervals proposed as part of the model test (e.g., measurement years) would remain the same length but each would start and end three months later. **CMS seeks comment on the alternative ETC model start date of April 1, 2020 and the corresponding 3-month delays.**

2. Defining ETC Model Participants (§§512.310, 512.325)

CMS proposes that *ETC participant* would mean an ESRD facility or Managing Clinician who is required to participate in the model. CMS further proposes to adopt the definition of *ESRD facility* found at 42 CFR 413.171, a definition that is used in the ESRD PPS and includes all

types of dialysis facilities appropriate for the ETC model.[42] CMS next proposes to define *Managing Clinician* as a Medicare-enrolled physician or non-physician practitioner who furnishes and bills the MCP for managing one or more adult ESRD beneficiaries. CMS regards this definition as sufficiently broad to capture the range of such clinicians found in the Medicare claims database. CMS proposes to require participation in the ETC model of all ESRD facilities and managing clinicians in selected geographic areas. Although several voluntary models already exist or have been announced involving ESRD care, CMS notes multiple advantages of a mandatory design, such as providing sufficient statistical power to assess model impacts on low-frequency events such as kidney transplants and allowing more rigorous model evaluation.

3. Selecting ETC Model Participants (§§512.310, 512.325)

CMS proposes to use Hospital Referral Regions (HRRs) as the geographic unit of participant selection. HRRs are groups of zip codes representing the referral patterns to tertiary care for Medicare beneficiaries. For the ETC model test, CMS would use HRRs derived from Medicare claims data, found in the Dartmouth Atlas Project at https://www.dartmouthatlas.org/. There are 306 such HRRs in the U.S.; the U.S. Territories would be excluded from selection as they were not included when Dartmouth's HRRs were constructed. Based upon projections about home dialysis and transplantation rate changes during the ETC model test and statistical power calculations (setting $\alpha = 0.05$ and $\beta = 0.80$), CMS proposes to draw participants from a random sample of 50 percent of HRRs (153 HRRs), stratified by the U.S. Census-defined regions.[43] The remaining HRRs would be designated as "comparison geographic areas" to be used during benchmark construction and during formal evaluation of the ETC model.

CMS describes having considered Core-Based Statistical Areas (CBSAs) or Metropolitan Statistical Areas (MSAs) as the geographic unit of selection but rejected them for failing to include rural areas. Also considered but not chosen were counties and states. Small county size would present many operational challenges (e.g., managing clinicians who practice in multiple counties), while state variations in population size and number of state-level ESRD-related regulations would introduce confounding factors. CMS would consider using CBSAs supplemented by assignment of rural counties to the nearest CBSA if HRR use proved infeasible.

CMS invites comment on 1) the choice of HRRs as the unit of selection and the alternative of CBSAs with added adjacent rural areas; and 2) the special HRR selection process for Maryland participants and whether similar adjustments should be made for the Pennsylvania Rural Health Model, the Vermont All-Payer ACO Model, or future state-based models.

[42] The definition reads as follows "an independent facility or a hospital-based provider of services (as described in 42 CFR 413.174(b) and (c)), including facilities that have a self-care dialysis unit that furnish only self-dialysis services as defined in §494.10 and meets the supervision requirements described in 42 CFR part 494, and that furnishes institutional dialysis services and supplies under 42 CFR 410.50 and 410.52".

[43] Maryland HRRs would be identified outside of the randomization due to an ongoing total cost of care model test in that state. All HRRs in which at least 20 percent of their component zip codes are located in Maryland would be selected for the ETC model test.

4. Identifying ETC Model Participants (§§512.310, 512.325)

CMS proposes that facility participants would be identified based on the zip code of their practice location addresses listed in the Medicare Provider Enrollment, Chain, and Ownership System (PECOS). Similarly, CMS proposes that managing clinician participants would be identified based on the zip code of their practice location addresses listed in PECOS. For both groups, CMS considered using the zip codes of their mailing addresses listed in PECOS, but regards the practice location as more reliable indicators of where ESRD care is delivered. **CMS invites comment on the use of practice location or mailing addresses.**

5. Home Dialysis Payment Adjustment (HDPA) ((§§512.340, 512.345, 512.350)

a. General Considerations

CMS proposes to make positive adjustments to payments for claims submitted by all facility and clinician ETC participants for home dialysis and related services with claim through dates during 2020, 2021, and 2022, the first three ETC model test years. The adjustment percentage would decline annually (3%, 2%, and 1%, respectively). The applicable adjustment percentage would apply to both 1) the clinician HDPA, made to the MCP; and 2) the facility HDPA, made to the Adjusted ESRD PPS per Treatment Base Rate. These calculations are described in more detail below. Neither HDPA adjustment would change beneficiary cost sharing. **CMS also proposes that both HDPA adjustments would apply when Medicare is the secondary payer and invites comment on this proposal.** CMS is not proposing a similar positive adjustment for transplant-related claims but instead proposes to implement a learning collaborative to disseminate best practices to increase the supply of deceased donor kidneys.

b. Applicable Payments, Payment Calculations, and Payment Schedule

Facility HDPA

CMS proposes to apply the facility HDPA to the Adjusted ESRD PPS per Treatment Base Rate on claim lines with Type of Bill 072X; when the type of facility code is 7 and the type of care code is 2, and with condition codes 74, 75, 76, or 80; and the beneficiary is age 18 or older during the entire month of the claim. These claim criteria would identify services furnished at or through ESRD facilities to a home dialysis beneficiary. Formulas for the current and the proposed HDPA-adjusted PPS per treatment amounts are shown below.

CMS considered adjusting the full per treatment amount by the HDPA but judged the proposed home dialysis incentive to be sufficient and invites comment on that decision.

$$\begin{aligned} Final\ ESRD\ PPS\ Per\ Treatment\ Payment\ Amount,\ \textbf{\textit{Current}} \\ = (Adjusted\ ESRD\ PPS\ Base\ Rate + Training\ Add\ On + TDAPA) \\ * ESRD\ QIP\ Factor \\ + Outlier\ Payment * ESRD\ QIP\ Factor \end{aligned}$$

$$\begin{aligned} &Final\ Per\ Treatment\ Payment\ Amount, with\ Facility\ HDPA \\ &\quad = ((Adjusted\ ESRD\ PPS\ per\ Treatment\ Base\ \ Rate \\ &\quad * Facility\ HDPA) + Training\ Add\ On + TDAPA) \\ &\quad * ESRD\ QIP\ Factor \\ &\quad + Outlier\ Payment * ESRD\ QIP\ Factor \end{aligned}$$

Clinician HDPA

CMS proposes to apply the clinician HDPA to the amount otherwise paid under Part B for MCP claims when claim lines contain CPT codes 90965 or 90966 (i.e., the amount otherwise paid is multiplied by the HDPA). These two CPT codes together describe all MCP claims for ESRD beneficiaries age 18 or older who receive home-dialysis services during the entire month of the claim. Applying the HDPA to the amount otherwise paid would avoid changes in beneficiary cost-sharing due to the clinician HDPA. CMS considered applying the HDPA to all claims billed by the managing clinician to an ESRD beneficiary (not just to dialysis management services) but judged the proposed incentive for home dialysis to be sufficient and **invites comment on that decision**.

Payment Schedule

CMS proposes that the HDPA percentage would decline over time for both the facility and clinician adjustments from 3% in CY 2020 to 1% in CY 2022 (as shown in Table 11 in the proposed rule and, reproduced below). This schedule allows for partial overlap of the HDPA with the Performance Payment Adjustment (PPA) during the course of the model test, which CMS believes would smooth the transition from the always-positive HDPA to the two-sided risk structure of the PPA. **CMS invites comments about the proposed schedule.**

TABLE 11: PROPOSED HDPA SCHEDULE

	CY 2020	**CY 2021**	**CY 2022**
Magnitude of Payment Adjustment	+3%	+2%	+1%

6. Performance Payment Adjustment (PPA) (§§512.355, 512.370, 512.375, 512.380)

a. General Considerations

The Performance Payment Adjustment (PPA) is designed to incent ETC participants to focus on care delivery strategies that could increase the home dialysis and transplantation rates in their own ESRD beneficiary populations. CMS proposes that PPA adjustments would be made during all years of the ETC model test and would apply to both: 1) the clinician PPA, made to the MCP; and 2) the facility PPA, made to the Adjusted ESRD PPS per Treatment Base Rate. As proposed, the PPA may be positive or negative (i.e., increase or decrease in actual payment) and the magnitude of the adjustment would increase over the duration of the ETC mode test.

CMS proposes a series of steps to calculate each participant's PPA: beneficiary attribution:

- performance assessment;
- risk adjustment;
- reliability adjustment; benchmark comparisons and Modality Performance Score (MPS) calculation; and
- PPA determination.

(Stepwise outlines of the PPA calculation processes are provided the end of section g below.)

b. Attribution

CMS proposes to attribute ESRD beneficiaries for each month of a 12-month Measurement Year (MY) to ETC participants based upon ESRD-related services received by beneficiaries during the month. CMS would attribute a beneficiary to no more than one facility and to no more than one clinician for given month. CMS proposed monthly attribution rather than annually to more accurately capture patient relationships to facilities and clinicians as changes occur. Prospective attribution was considered before the start of each MY but judged inappropriate given ongoing attrition of beneficiary populations through death and transplantation throughout the MY. CMS also proposes to attribute "pre-emptive beneficiaries", defined as those receiving kidney transplants before ever starting any form of dialysis, but only to clinicians and not to facilities. CMS proposes criteria to exclude ESRD and pre-emptive beneficiaries from attribution for any month in which the beneficiary: (1) is not enrolled in Medicare Part B; (2) is enrolled in a Medicare managed care plan (e.g., MA); (3) resides outside of the U.S.; (4) is under age 18; (5) has elected hospice; (6) is receiving dialysis for acute kidney injury (AKI) only; or (7) has a diagnosis of dementia. CMS considered an age cut-off and housing insecurity as exclusions for home dialysis attribution but could not identify consensus values for an age cut-ff or objective definitions for housing insecurity from the medical literature. **CMS seeks input on potential ways to account for age and housing insecurity effects on home dialysis rates**.

CMS proposes to attribute eligible beneficiaries to the facilities at which they received the plurality of their dialysis treatments for the month and to the clinician who submits an MCP claim for that month. The pre-emptive transplant beneficiary is attributed, for all months between the start of the MY and the month of the transplant, to the clinician with whom the beneficiary had the most claims between the MY start and the transplant month. Finally, CMS proposes to provide participants with lists of their attributed beneficiaries after attribution is completed for each MY. CMS considered basing attribution on a minimum number of treatments rather than plurality, but thought this to less accurately reflect care delivery. Deferring attribution until after a minimum period of dialysis was also discarded since decisions about dialysis options, an important focus of the ETC model, are often made in those early months.

CMS seeks comment on its attribution approach, especially the decision not to attribute pre-emptive beneficiaries to facilities.

c. Performance assessment

CMS proposes to address separately the home dialysis and transplant rates for each ETC participant's attributed population for each 12-month MY using Medicare claims and administrative data plus data from the Scientific Registry of Transplant Recipients (SRTR).

Facility home dialysis rate = *Home dialysis treatment beneficiary years / Total dialysis treatment beneficiary years*

Clinician home dialysis rate = *Home dialysis treatment beneficiary years / Total dialysis treatment beneficiary years*

Beneficiary years for the home dialysis rates above would be composed of months of dialysis for all attributed ESRD beneficiaries during the MY, and a beneficiary year would be composed of 12 beneficiary months. Total dialysis treatment years would include all forms of maintenance dialysis. Treatment months would be identified using Type of Bill 072X for facilities and professional claims containing CPT codes for dialysis services.

Facility transplant rate = *Total number of attributed beneficiaries receiving a transplant anytime during the MY / Total dialysis treatment beneficiary years*

Clinician transplant rate = *(Total number of attributed beneficiaries receiving a transplant anytime during the MY + the number of attributed pre-emptive transplant beneficiaries) / (Total dialysis treatment beneficiary years + total number of attributed beneficiary years for preemptive transplant beneficiaries)*

Beneficiary years for the transplant rates above also would be composed of months of dialysis for all attributed ESRD beneficiaries during the MY, and a beneficiary year would be composed of 12 beneficiary months. Total dialysis treatment years would include all forms of maintenance dialysis. Treatment months would be identified by using Type of Bill 072X for facilities and professional claims containing CPT codes for dialysis services. Bills and claims involving beneficiaries 75 years or older or who were in a SNF at any point during a month would be excluded as these beneficiaries are unlikely to be transplant candidates. Transplant procedures would be identified using MS-DRGs, ICD-10-PCS procedure codes, and SRTR data for both facility and clinician rate calculations. CMS considered using transplant waitlisting rates rather than transplant rates but opted to propose an outcome rather than process measure. CMS also considered using multiple years of data for transplant rate calculations since transplants are relatively rare events but opted to base the rate on one MY given the counterbalancing effects of the proposed reliability adjustment. **CMS invites comment on the proposed transplant rate calculations.**

Payments ultimately would be adjusted using the PPA during distinct PPA periods, each 6-months long and each linked to a specific MY. Overlap across MYs would allow rolling updates. (See Table 12 from the rule provided later in this section.)

d. Risk adjustment

CMS proposes to use the CMS-HCC (Hierarchical Condition Category) ESRD Dialysis Model to risk adjust the home dialysis rates for both clinicians and facilities. The most recent final risk score available for the beneficiary at the time of rate calculation would be used. Risk adjustment of the clinician and facility transplant rates uses beneficiary age categories that each have separate risk coefficients and are similar to the categories used for the Percentage of Prevalent Patients Waitlisted (PPPW) measure with which ETC participants would already have familiarity. The transplant rate is adjusted to account for the relative percentage of the population of beneficiaries attributed to the ETC Participant in each age category relative to the national age distribution of beneficiaries not excluded from attribution. CMS considered construction of risk adjustment models customized for ETC model use but believes the HCC ESRD Dialysis Model to be sufficiently robust for the ETC home dialysis model test.

e. Reliability adjustment

CMS proposes applying reliability adjustments separately to each facility participant's home dialysis and transplant rates. These adjustments are targeted at smoothing the substantial rate variability introduced by the small numbers for home dialysis and transplantation that can be attributed to any given participant during each MY. The adjustment takes into account an individual participant's facility rate compared to that of its aggregation group. CMS does not provide full details of how the adjustment would be calculated but does indicate that facilities would be placed into "credibility group tiers" based upon their total dialysis treatment beneficiary years and their HRRs. The aggregation group for a subsidiary ESRD facility would include all facilities owned in whole or in part by the same legal entity located in the HRR in which the measured facility is located. The aggregation group for a facility that is not a subsidiary facility would include all facilities located in the HRR in which the measured facility is located, with the exception of subsidiary ESRD facilities.

CMS also proposes that managing clinician participant home dialysis and transplant rates would be reliability-adjusted. These adjustments are targeted to similar rate variability concerns and would be made in the same general manner as outlined above for facilities. Home dialysis rates and transplant rates would first be grouped at the practice group level (by practice TIN) for clinicians in a group practice, and at the individual NPI level for solo practitioners. Performance would then be aggregated. The aggregation group for group practice clinicians would be all managing clinicians within the HRR in which the group practice is located. The aggregation group for solo practitioners would be all managing clinicians within the HRR in which the measured clinician is located. CMS ends by noting similar uses of reliability adjustments and aggregation in other program calculations such as Hospital Compare ratings.

f. Benchmarking and MPS Scoring (§512.370)

For achievement scoring, CMS proposes to compare ETC model participants' home dialysis and transplant rates against benchmarks that would be derived using the corresponding rates calculated for the nonparticipant facilities and clinicians in the HHRs not selected for mandatory ETC participation. Initial benchmarks would be derived from historical data from the comparison areas. For improvement scoring, CMS proposes to compare home dialysis and transplant rates of ETC model clinician and facility participants against benchmarks that would be constructed from their own corresponding historical rates for the benchmark year. Benchmarks for both scores would be updated on a rolling basis thereafter. The proposed scoring methodology is presented in the rule as Table 13, reproduced below. **CMS considered deferring improvement scoring during the first two MYs and invites comment on this subject.**

TABLE 13: PROPOSED SCORING METHODOLOGY FOR ASSESSMENT OF MEASUREMENT YEARS 1 AND 2 ACHIEVEMENT SCORES AND IMPROVEMENT SCORES ON THE HOME DIALYSIS RATE AND TRANSPLANT RATE

Achievement Score Scale for MYs 1 & 2	Points	Improvement Score Scale for MYs 1 & 2
90th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	2	Not a scoring option
75th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	1.5	Greater than 10% improvement relative to benchmark year rate
50th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	1	Greater than 5% improvement relative to benchmark year rate
30th+ Percentile of benchmark rates for comparison geographic areas during the benchmark year	0.5	Greater than 0% improvement relative to benchmark year rate
<30th Percentile of benchmark rates for	0	Less than or equal to benchmark year rate
comparison geographic areas during the benchmark year		

CMS further proposes to calculate a Modality Performance Score (MPS) for each participating clinician and facility according to the formula below, with relative weights of 2:1 for the home dialysis and transplant rates.

$$\textit{Modality Performance Score} = 2 \times (\textit{Higher of home dialysis rate achievement or improvement score}) + (\textit{Higher of transplant rate achievement or improvement score})$$

The MPS is linked to the PPA measurement years and PPA periods as shown in Table 12, reproduced below from the rule.

TABLE 12: ETC MODEL SCHEDULE OF MEASUREMENT YEARS AND PPA PERIODS

	Measurement Year (MY)		**Performance Payment Adjustment (PPA) Period**	
Beginning CY 2020	MY 1	1/1/2020 through 12/31/2020	PPA Period 1	7/1/2021 through 12/31/2021
	MY 2	7/1/2020 through 6/30/2021	PPA Period 2	1/1/2022 through 6/30/2022
Beginning CY 2021	MY 3	1/1/2021 through 12/31/2021	PPA Period 3	7/1/2022 through 12/31/2022
	MY 4	7/1/2021 through 6/30/2022	PPA Period 4	1/1/2023 through 6/30/2023
Beginning CY 2022	MY 5	1/1/2022 through 12/31/2022	PPA Period 5	7/1/2023 through 12/31/2023
	MY 6	7/1/2022 through 6/30/2023	PPA Period 6	1/1/2024 through 6/30/2024
Beginning CY 2023	MY 7	1/1/2023 through 12/31/2023	PPA Period 7	7/1/2024 through 12/31/2024
	MY 8	7/1/2023 through 6/30/2024	PPA Period 8	1/1/2025 through 6/30/2025
Beginning CY 2024	MY 9	1/1/2024 through 12/31/2024	PPA Period 9	7/1/2025 through 12/31/2025
	MY 10	7/1/2024 through 6/30/2025	PPA Period 10	1/1/2026 through 6/30/2026

g. Final PPA determination

CMS also proposes to determine the PPAs for facilities and clinicians as shown in Tables 14 and 15 reproduced below from the rule. Higher negative risk percentages are proposed by CMS for facilities as those entities are thought capable of greater risk-bearing than small clinician groups. **CMS also proposes to apply the facility PPA to claims where Medicare is the secondary payer and seeks comment on this decision.** The clinician PPA would be linked to the amount otherwise paid under Part B to avoid changes to beneficiary cost-sharing, as proposed for the HDPA.

TABLE 14: PROPOSED FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

		Performance Payment Adjustment Period				
	MPS	**1 and 2**	**3 and 4**	**5 and 6**	**7 and 8**	**9 and 10**
	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%

	MPS	Performance Payment Adjustment Period				
		1 and 2	**3 and 4**	**5 and 6**	**7 and 8**	**9 and 10**
Facility Performance Payment Adjustment	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-4.0%	-4.5%	-5.0%	-6.0%	-6.5%
	≤ .5	-8.0%	-9.0%	-10.0%	-12.0%	-13.0%

TABLE 15: PROPOSED CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

	MPS	Performance Payment Adjustment Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Clinician Performance Payment Adjustment	≤ 6	+5.0%	+6.0%	+7.0%	+8.0%	+10.0%
	≤ 5	+2.5%	+3.0%	+3.5%	+4.0%	+5.0%
	≤ 3.5	0.0%	0.0%	0.0%	0.0%	0.0%
	≤ 2	-3.0%	-3.5%	-4.0%	-4.5%	-5.5%
	≤ .5	-6.0%	-7.0%	-8.0%	-9.0%	-11.0%

Outline of PPA calculation processes

Facility

1. Assess the home dialysis and transplant rates using the formulas based upon beneficiary dialysis treatment years, provided in section c above.

2. Risk adjust the rates.
   a. For the home dialysis rate, use the most recently available CMS-HCC ESRD Dialysis Model scores for each attributed beneficiary.
   b. For the transplantation rate, use beneficiary age and PPPW as described in section d above.

3. Perform reliability adjustment of the rates as discussed in section e above taking into account the facility's volume of beneficiary dialysis treatment years and the HRR in which it is located in relationship to the rates for the facility's aggregation group. Note that aggregation groups are different for subsidiary and non-subsidiary ESRD facilities.

4. Calculate achievement and improvement scores for the facility for each rate as discussed in section f above and shown in Table 13.

5. Calculate the Modality Performance Score (MPS) for the facility as described in section f above. Find the applicable MY and PPA adjustment period from Table 12.

6. Find the facility PPA amount from Table 14 using the MPS for the applicable PPA period.

Clinician

1. Assess the home dialysis and transplant rates using the formulas based upon beneficiary dialysis treatment years, provided in section c above.

2. Risk adjust the rates.
   a. For the home dialysis rate, use the most recently available CMS-HCC ESRD Dialysis Model scores for each attributed beneficiary.
   b. For the transplantation rate, use beneficiary age and PPPW as described in section d above.

3. Perform reliability adjustment of the rates as discussed in section e above taking into account the clinician (NPI-level) or practice group's (TIN-level) volume of beneficiary dialysis treatment years and the HRR in which it is located, in relationship to the rates for the corresponding aggregation group. The aggregation group for solo clinicians and for practice groups is the same: all managing clinicians in the HRR, regardless of solo or group practice status.

4. Calculate achievement and improvement scores for the clinician for each rate as discussed in section f above and shown in Table 13.

5. Calculate the Modality Performance Score (MPS) for the clinician as described in section f above. Find the applicable MY and PPA adjustment period from Table 12.

6. Find the facility PPA amount from Table 15 using the MPS for the applicable PPA period.

h. PPA Low-Volume Exclusions

CMS proposes to define a low-volume facility as one having less than 11 attributed beneficiary-years, or less than 132 attributed beneficiary-months, during a given MY. A facility meeting this criterion would be exempt from the PPA during the PPA period corresponding to the low-volume MY. CMS chose the 11-year threshold because of its similarity to the 11-patient threshold used in the ESRD QIP when scoring certain measures. CMS considered adopting the 11-patient minimum but states that methodological differences in attribution between the QIP and the ETC favor the use of the 11-year threshold for the ETC. **CMS invites comments on the low-volume threshold and the cut-point to be used for facilities.**

CMS also proposes to set a low-volume threshold for application of the clinician PPA. Low-volume clinicians may serve niche populations (e.g., very rare childhood kidney diseases) that could impact the model's results. CMS proposes setting the clinician low-volume threshold to include the bottom five percent of ETC clinicians, using the number of beneficiary-years for which the clinician billed the MCP during the MY. CMS considered implementing a threshold expressed in total dollar value of Medicare claims paid but the wide variation in services and associated payment rates represented in this diverse clinician population argues against this

approach. **Nevertheless, CMS invites comment on the proposed clinician low-volume threshold and alternatives considered.**

i. Notification

During the first 6 months after a MY ends CMS calculates and validates the MPS and associated PPA for each ETC model participant. CMS proposes to notify participants about their attributed beneficiaries, MPS, and PPA for the upcoming PPA period at least one month prior to the PPA period start date (5 months after the MY ends). CMS would determine the form and manner of the notification.

j. Targeted Review

CMS proposes a process through which an ETC model participant can request a targeted MPS calculation review. The request's scope would be limited to MPS scoring. Out-of-scope items would include: MPS dialysis rate and transplant rate methodology; achievement and improvement benchmarking methodology; and PPA amounts. Proposed elements of the review process would include:

- The targeted review must be requested by the participant within 60 days of receiving the MPS result. The participant may include additional information with the review request.
- CMS would review requests promptly to determine if reviews are warranted.
- Any supplemental information requested by CMS must be provided by the participant within 30 days or the case will be closed.
- Should an MPS error be identified that has resulted in incorrect payment during the PPA period, CMS would work with the participant to correct the MPS error and associated PPA adjustment.
- Decisions related to targeted review are final and exempt from appeal.
- Normal claims processes may be utilized by ETC participants to dispute Medicare FFS claims during the model test period (e.g., through the MACs).

CMS considered compressing the process timeline but decided no value was gained by doing so.

7. Overlap of ETC with Other CMS Initiatives

- As noted previously, CMS has proposed that the HDPA and PPA for facilities would be applied prior to application of the ESRD QIP payment adjustment to the ESRD PPS per treatment; the HDPA and PPA would be applied to the Adjusted ESRD PPS per Treatment Base Rate.
- MIPS-eligible managing clinicians would remain subject to MIPS. The HDPA and PPA for clinicians would apply to the amount otherwise paid under Part B but would be applied prior to application of the MIPS payment adjustment factors.
- Since the Comprehensive ESRD Care model test will be complete at the end of 2020, overlap with the ETC should be minimal. CMS states that ETC participants could be selected from HRRs in which CEC ESRD Seamless Care Organizations currently provide care.

- Payment adjustments made under the ETC model would be counted as expenditures under the Medicare Shared Savings Program and other CMS total-cost-of-care-initiatives.
- ETC participants will be able to join entities formed under the newly-announced Kidney Care First and Comprehensive Kidney Care Contracting voluntary models.

8. Medicare Program Waivers (§512.397)

CMS proposes to waive the requirements of sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act only to the extent necessary to make the payment adjustments under the ETC Model as described in this rule.

To test the impact of broadening the KDE benefit on beneficiary renal replacement therapy choices, CMS proposes the following waivers:

- CMS waives the requirement that only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services under section 1861(ggg)(2)(A)(i) of the Act and § 410.48(c)(2)(i) of this chapter to allow KDE services to be provided by clinical staff under the direction of and incident to the services of the managing clinician who is an ETC Participant;
- CMS waives the requirement that the KDE is covered only for Stage IV CKD patients under section 1861(ggg)(1)(A) of the Act and § 410.48(b)(1) of this chapter to permit beneficiaries diagnosed with CKD Stage V or within the first 6 months of receiving a diagnosis of ESRD to receive the KDE benefit;
- CMS waives the requirement that the content of the KDE sessions include the management of co-morbidities, including delaying the need for dialysis, under §410.48(d)(1) of this chapter when such services are furnished to beneficiaries with CKD Stage V or unless such content is relevant for the beneficiary; and
- CMS waives the requirement that an outcomes assessment designed to measure beneficiary knowledge about CKD and its treatment be performed by qualified clinician as part of one of the KDE sessions under § 410.48(d)(5)(iii) of this chapter, provided that such outcomes assessment is performed within one month of the final KDE session by qualified staff.

9. Quality Monitoring (§512.395)

CMS proposes two ESRD facility quality measures for reporting during the ETC model test:

- Standardized Mortality Ratio (SMR); NQF #0369 – Risk-adjusted standardized mortality ratio of the number of observed deaths to the number of expected deaths for patients at the ESRD facility, and
- Standardized Hospitalization Ratio (SHR); NQF #1463 – Risk-adjusted standardized hospitalization ratio of the number of observed hospitalizations to the number of expected hospitalizations for patients at the ESRD facility.

Both measures are currently calculated and displayed by CMS on Dialysis Facility Compare. The SHR also is part of the ESRD QIP set of measures. CMS states that monitoring these two measures will aid in the early detection of unintended consequences of the ETC model test. Performance on these measures will not be tied to payment under the ETC model, and the model as proposed does not meet criteria to be considered an Advanced APM. **CMS invites comment on the proposal not to tie quality measurements directly to the ETC payment adjustments.**

10. Overlap with General Provision of the Proposed Rule (Section II of the rule)

a. Monitoring Activities

CMS expands the discussion of the monitoring activities as described earlier (sections II.E and II.H of the rule). Highlights include development of longer-term analytic strategies allowing detection of more subtle impacts of the model (positive and negative); increasing focus on unintended consequences by monitoring the rate of in-center backup dialysis for home dialysis patients treated under the model; seeking input on detection of issues with home dialysis equipment; and expanding data sources and items to be monitored for beneficiaries receiving transplants during the ETC model test. **CMS invites comment on the expanded monitoring plan.**

b. Beneficiary Notification about the Model Test (§512.330)

CMS reprises that ETC participants would be required to prominently display in each of their offices or facility locations where beneficiaries receive treatment, informational materials that notify beneficiaries that some of their healthcare providers are participating in the ETC Model test. CMS intends to provide a template for these materials that would include instructions for beneficiaries on how to access the ESRD Network Organizations with any concerns about their providers' ETC participation.
[44] These template materials would be exempt from the proposed requirement that descriptive model materials are subject to CMS review.

c. Evaluation

CMS expands on discussion earlier in the rule concerning formal evaluation of Innovation Center models. CMS plans to select an independent contractor to evaluate the ETC model. Potential research questions would include whether or not the ETC Model results in a higher rate of transplantation and home dialysis, better quality of care and quality of life, and reduced utilization and expenditures for beneficiaries in selected geographic areas in relation to comparison geographic areas. The evaluation would also explore qualitatively what changes managing clinicians and ESRD facilities implemented in response to the ETC Model, what challenges they faced, and lessons learned to inform future policy developments. CMS proposes

[44] The 18 ESRD Network Organizations operate under contracts with CMS and serve distinct geographical Regions. Responsibilities include oversight of the quality of care given to ESRD patients, the collection of data to administer the national Medicare ESRD program, and the provision of technical assistance to ESRD providers and patients in areas related to ESRD)

a mixed- methods approach to the ETC evaluation that includes qualitative and quantitative data analyses, including a difference-in-differences or similar methodology. CMS proposes that the comparison group for purpose of model evaluation will be drawn from HRRs not selected for mandatory model participation and include propensity scoring. **CMS invites comment on the evaluation plan as outlined.**

d. Learning System

CMS describes a plan to operate a voluntary learning system for ETC participants focused on increasing the availability of deceased donor kidneys. Attention would be placed upon sharing best practices and involving a diverse stakeholder group (e.g., including organ procurement organizations).

V. Regulatory Impact

A. Statement of Need

CMS discusses the reasons why the proposed RO model is needed. CMS believes that the incentive to provide more radiation therapy services is misaligned with evidence-based practice, which is moving towards furnishing fewer radiation treatments for certain cancer types. It also expresses concern about the difficulties in coding and setting payment rates for RT services under the Medicare PFS and the increasing coding and administrative burden. CMS believes that the RO model design would lead to higher quality care and provide participants the opportunity to earn back a withheld payment amount through successful quality outcomes and clinical data reporting. RO participants would be required to collect and submit quality data on quality measures, clinical data, and patient experience throughout the course of the RO Model beginning January 1, 2020, with the final data submission ending in 2025.

CMS also discusses the need for the proposed End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model. As described earlier, CMS believes that the current Medicare payment rules and a deficit in beneficiary education result in a bias toward in-center hemodialysis rather than home dialysis or kidney transplantation. It believes that the evidence supports the conclusion that higher rates of home dialysis and kidney transplants would reduce Medicare expenditures and enhance beneficiary choice, independence, and quality of life.

B. Overall Impact

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity).[45] A regulatory impact analysis (RIA) must be prepared

[45] Impact assessments of this rule are required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security

for rules that result in a "significant regulatory action". CMS estimates that this rulemaking meets the criteria for a major rule. Accordingly, CMS prepared a Regulatory Impact Analysis to present the costs and benefits of the rulemaking.

C. Anticipated Effects

1. Effect of the Medicare Program

CMS estimates that the combined financial impact of the proposed RO Model and the ETC Model would be a net federal savings of $429 million over a 5 –year performance period (2020 through 2024). Detailed estimates and assumptions are discussed below.

a. Radiation Oncology Model

CMS notes that the RO Model as proposed would include 40 percent of radiation oncology episodes in eligible geographic areas. In a simulation of this model, CMS randomly selected CBSAs and found that there would be 616 PGPs (slightly over half, 325, of these were freestanding radiation therapy centers) and 541 HOPDs furnishing RT services in those simulated selected CBSAs. If finalized, as proposed with the RO Model starting in January 2020, the model would have a 5-year performance period and include an estimated 364,000 episodes, 322,000 beneficiaries, and $5.4 billion in total episode spending of allowed charges (inclusive of beneficiary cost sharing).

Table 16A in the proposed rule (reproduced below) summarizes the estimated impact of the proposed RO Model based on a January 1, 2020 start date.[46] CMS estimates that on net the Medicare program would save $260 million over the 5 performance years (2020 through 2024). This is the net Medicare Part B impact that includes both Part B premium and MA rate financing interaction effects. CMS projects that 82 percent of physician participants (as measured by unique NPI) would receive the APM incentive payment under the Quality Payment Program at some point during the model performance period. The APM incentive payment, as proposed, would apply only to the professional episode payment amounts and not the technical episode payment amounts. In addition, no APM incentive payments would be paid based on participation in the RO Model in 2020 and 2021, due to the two-year lag between the QP performance and payment periods.

Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

[46]CMS also provides estimates based on a April 1, 2020 start date in Table 16B

Table 16A: Proposed Estimates of Medicare Program Savings (Millions $) for Proposed Radiation Oncology Model (Starting January 1, 2020)

	Year of Proposed Model					
	2020	**2021**	**2022**	**2023**	**2024**	**5-Year Total***
Net Impact To Medicare Program Spending	-40	-50	-50	-60	-60	-260
Changes to Incurred FFS Spending	-30	-40	-40	-40	-50	-200
Changes to MA Capitation Payments	-20	-30	-30	-30	-40	-150
Part B Premium Revenue Offset	10	10	20	20	20	80
Total APM Incentive Payments	0.0	0.0	4.0	4.0	4.0	12.0
Episode Allowed Charges	1,010	1,050	1,080	1,110	1,140	5,390
Episode Medicare Payment	790	820	840	870	890	4,200
Total Number of Episodes	70,000	71,000	73,000	74,000	76,000	364,000
Total Number of Beneficiaries	68,000	69,000	71,000	72,000	74,000	322,000

*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

To calculate these numbers, CMS use a stochastic simulation to estimate the financial impacts of the proposed RO Model relative to baseline assumptions. The model relied on data from retrospectively constructed RT episodes between 2015 and 2017. Among other assumptions, CMS assumed that traditional FFS payment system billing patterns continued under current law and that net OPPS updates would outpace the PFS by 3.0 percent on average annually between 2019 and 2024. CMS also stresses that a key assumption of its impact analyses is that the volume and intensity (V&I) of the bundled services per episode remains unchanged between the period used for rate setting and when payments are made. If V&I were to decrease annually for the bundled services absent the model, then Medicare would only reduce net outlays by $50 million, and conversely if the V&I growth increases by 1.0 percent annually, then net outlays would be reduced by $460 million.

b. ESRD Treatment Choices Model

The ETC model, as proposed, would include 50 percent of ESRD beneficiaries through the ESRD facilities and Managing Clinicians selected for participation in the model. CMS notes that only about 10 percent of beneficiaries received home dialysis in 2017. The payment adjustments proposed for the ETC model is expected to include an estimated 3,548 ESRD facilities, 3,642 Managing Clinicians, 216,218 beneficiaries, and $169 million in net Medicare savings.

Table 17 in the proposed rule (reproduced below) summarizes the estimated impact of the proposed ETC Model. This assumes a rolling benchmark where the achievement benchmarks for each year are set using the average of the home dialysis rates for year t-1 and year t-2 for the HRRs randomly selected for participation in the ETC model. CMS estimates that the Medicare program would save a net total of $185 million from the PPA and HDPA between January 1, 2020 and June 30, 2026, less $15 million in increased training and education expenditures. As expected, the Medicare program savings were driven by the net effect of the ESRD facility PPA;

a reduction of $220 million over this period compared with $8 million in savings from the Managing Clinician PPA.

Table 17. Proposed Estimates of Medicare Program Savings (Rounded $M) for Proposed ESRD Treatment Choices Model

	Year of Proposed Model							
	2020	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**6.5 Year Total***
Net Impact to Medicare Spending	20	1	-22	-36	-49	-57	-26	**-169**
Overall PPA Net & HDPA	19	-1	-24	-38	-52	-60	-29	**-185**
Clinician PPA Downward Adjustment		-2	-6	-7	-8	-10	-6	-38
Clinician PPA Upward Adjustment		2	5	6	6	8	4	31
Clinician PPA Net		-1	-1	-1	-2	-2	-1	-8
Clinician HDPA	2	1	1					4
Facility Downward Adjustment		-34	-76	-93	-114	-137	-73	-528
Facility Upward Adjustment		18	45	56	64	80	45	307
Facility PPA Net		-15	-32	-38	-51	-57	-28	-220
Facility HDPA	17	14	8					39
Total PPA Downward Adjustment		-36	-82	-100	-122	-147	-79	-566
Total PPA Upward Adjustment		20	49	61	70	87	49	338
Total PPA Net		-16	-32	-38	-52	-60	-29	-228
Total HDPA	19	15	9					43
KDE Benefit Costs	0	1	1	1	1	1	1	**5**
HD Training Costs	1	1	1	1	2	2	2	**10**

*Totals may not sum due to rounding and from beneficiaries that have dialysis treatment spanning multiple years. Negative spending reflects a reduction in Medicare spending.

CMS states that the results were generated from an average of 500 simulations. The key assumption underlying the impact estimate is that each ESRD facility or Managing Clinician's share of total maintenance dialysis provided in the home setting was assumed to grow at a maximum growth averaging 3 percentage points per year. CMS notes that this 3-percentage point per year max growth rate would in effect move the average market peritoneal dialysis rate (about 10 percent) to the highest market baseline peritoneal dialysis rate (Bend Oregon HRR at about 25 percent), which it believes is a reasonable upper bound growth estimate.

CMS also performed a sensitivity analysis where benchmarks remain fixed at baseline year 0 over time. CMS notes that the fixed benchmark would allow the ESRD facilities and Managing

Clinicians to have more favorable achievement and improvement scores over time compared to the rolling benchmark method. As result, this approach would generate $189 million in losses, compared to a total of $185 million in savings with the rolling benchmark method.

CMS also estimated the effects on kidney transplantation. CMS notes that it decided to be conservative and did not include an assumption that the overall number of kidney transplants will increase. It did estimate that the ETC model would produce an average 10-year savings to Medicare of about $32,000 per beneficiary for deceased donor kidney transplantation with high-Kidney Donor Profile Index (KDPI) organs. Specifically, CMS assumes an increase in marginal kidney utilization such that the national discard rate would drop to 15 percent by the end of the model testing period – about 2,360 additional transplants and an estimate $76 million in federal savings.

CMS also estimates the 7-year total in home dialysis training costs to be $10 million assuming a stable 3 percent growth rate in the use of home dialysis per year.

2. Effects on Medicare Beneficiaries

CMS anticipates that the RO Model would benefit or have a negligible impact on the cost to beneficiaries receiving RT services. Beneficiaries would be responsible for 20 percent of each of the PC and TC episode payments made under the RO Model, as under current policy for those services paid for under the OPPS and Medicare PFS, respectively. CMS believes based on the application of the discount factor (4 percent for PC and 5 percent for TC), the beneficiary cost-sharing, on average, would be reduced relative to what typically would be paid under traditional Medicare FFS for an episode of care.

With respect to the ETC Model, CMS also anticipates that the model will have a negligible impact on the cost to beneficiaries receiving dialysis. CMS notes that beneficiaries would be held harmless from the application of the Clinician PPA and the Clinician HDPA, and beneficiaries would also be held harmless from the Facility PPA and HDPA adjustments. It also cites various studies concluding that the beneficiary's quality of life has the potential to improve with home dialysis as opposed to in-center dialysis.

3. Effects on RO and ETC Participants

CMS provides burden estimates of understanding and meeting the requirements for the RO model and the ETC Model,

- CMS estimates that the total cost of learning the billing system for the RO Model is $144.34 per participant, or approximately $167,000 in total. Because the ETC model does not alter the way ETC participants bill Medicare, CMS believes there is no additional burden for ETC participants.
- With respect to monitoring and compliance requirements, CMS does not anticipate any additional burden or regulatory impact on participants in either the RO or ETC model. For model evaluation, CMS anticipates that both models would likely include

beneficiaries and providers completing surveys, but does not estimate the burden. The burden, however, would depend on the length, complexity and frequency of the surveys.

- For quality measure and clinical data element reporting, CMS estimates that reporting these elements for the RO model would be about $388 per entity per year or a total $449,000 for the estimated 1,157 RO Model participants. The ETC model, however, does not require an additional quality measure or clinical data element reporting by ETC participants, and thus no additional burden.
- CMS anticipates that the total burden estimate for reading and interpreting the RO Model rule would be $1.35 million and $6.7 million for the ETC Model.

4. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities. The Secretary has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

For the RO Model, CMS states that the majority of HOPDs and other RT providers and RT suppliers are small entities. CMS estimates that, on average, Medicare FFS payments to PGPs would be reduced by 5.9 percent and 4.2 percent for HOPDs. Because this model is limited to only Medicare FFS beneficiaries, not other payers including Medicare Advantage and commercial insurers, CMS expected the anticipated average impact of revenue based solely on Medicare FFS payments to be less than 1 percent. This does not meet the greater than 5 percent threshold to be economically significant. CMS estimates that complying with the quality measure and clinical data element reporting to be about $388 per entity per year. It estimates the administrative cost of reading and interpreting this proposed rule per small entity to be about $444.89.

For the ETC Model, it assumes that the great majority of Managing Clinicians would be small entities and that the greater majority of ESRD entities would not be small entities. CMS concludes that the proposed low volume threshold exclusions, risk adjustments, and reliability adjustments only affect payment for selected services and thus would not have a greater than 5 percent impact on a substantial number of small entities

5. Other Effects

CMS also determines that the proposed RO Model and ETC model would not have a significant impact on the operations of a substantial number of small rural hospitals, does not mandate any requirements for State, local, or tribal governments, or for the private sector. It also determines that this rule would not have a substantial direct effect on state or local governments, preempt state law, or otherwise have a Federalism implication.

6. Accounting Statements.

Tables 18 and 19 in the proposed rule show the classifications of transfers, benefits, and costs associated with the provisions of the proposed rule.

APPENDIX VI

TABLE 2-LIST OF RO MODEL BUNDLED HCPCS

HCPCS	HCPCS Description	Category
55920	Placement Pelvic Needles/Catheters, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57155	Placement Tandem and Opioids, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
57156	Placement Vaginal Cylinder, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
58346	Placement Heyman Capsules, Brachytherapy	Radiation Treatment Delivery (Brachytherapy Surgery)
77014	Computed tomography guidance for placement of	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77021	Magnetic resonance guidance for needle placement	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77261	Radiation therapy planning	Treatment Planning
77262	Radiation therapy planning	Treatment Planning
77263	Radiation therapy planning	Treatment Planning
77280	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77285	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77290	Set radiation therapy field	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77293	Respirator motion mgmt simul	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77295	3-d radiotherapy plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77299	Radiation therapy planning	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77300	Radiation therapy dose plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77301	Radiotherapy dose plan imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77306	Telethx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77307	Telethx isodose plan cplx	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77316	Brachytx isodose plan simple	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77317	Brachytx isodose intermed	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77318	Brachytx isodose complex	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77321	Special teletx port plan	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77331	Special radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77332	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services

HCPCS	HCPCS Description	Category
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery
77387	Guidance for radiaj tx dlvr	Radiation Treatment Delivery (Guidance)
77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77424	Io rad tx delivery by x-ray	Radiation Treatment Delivery
77425	Io rad tx deliver by elctrns	Radiation Treatment Delivery
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery
77522	Proton trmt simple w/comp	Radiation Treatment Delivery
77523	Proton trmt intermediate	Radiation Treatment Delivery
77525	Proton treatment complex	Radiation Treatment Delivery
77761	Apply intrcav radiat simple	Radiation Treatment Delivery
77762	Apply intrcav radiat interm	Radiation Treatment Delivery
77763	Apply intrcav radiat compl	Radiation Treatment Delivery
77767	Hdr rdncl skn surf brachytx	Radiation Treatment Delivery
77768	Hdr rdncl skn surf brachytx	Radiation Treatment Delivery
77770	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77771	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77772	Hdr rdncl ntrstl/icav brchtx	Radiation Treatment Delivery
77778	Apply interstit radiat compl	Radiation Treatment Delivery
77789	Apply surf ldr radionuclide	Radiation Treatment Delivery
77790	Radiation handling	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77799	Radium/radioisotope therapy	Radiation Treatment Delivery
A9527	Iodine i-125 sodium iodide	Radiation Treatment Delivery (Brachytherapy Materials)
C1715	Brachytherapy needle	Radiation Treatment Delivery (Brachytherapy Materials)
C1716	Brachytx, non-str, gold-198	Radiation Treatment Delivery (Brachytherapy Materials)

HCPCS	HCPCS Description	Category
C1717	Brachytx, non-str,hdr ir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1719	Brachytx, ns, non-hdrir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1728	Catheter, brachytherapy seed administration	Radiation Treatment Delivery (Brachytherapy Materials)
C2616	Brachytx, non-str,yttrium-90	Radiation Treatment Delivery (Brachytherapy Materials)
C2634	Brachytx, non-str, ha, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2635	Brachytx, non-str, ha, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2636	Brachy linear, non-str,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2638	Brachytx, stranded, i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2639	Brachytx, non-stranded,i-125	Radiation Treatment Delivery (Brachytherapy Materials)
C2640	Brachytx, stranded, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2641	Brachytx, non-stranded,p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2642	Brachytx, stranded, c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2643	Brachytx, non-stranded,c-131	Radiation Treatment Delivery (Brachytherapy Materials)
C2644	Brachytx cesium-131 chloride	Radiation Treatment Delivery (Brachytherapy Materials)
C2645	Brachytx planar, p-103	Radiation Treatment Delivery (Brachytherapy Materials)
C2698	Brachytx, stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
C2699	Brachytx, non-stranded, nos	Radiation Treatment Delivery (Brachytherapy Materials)
G0339	Robot lin-radsurg com, first	Radiation Treatment Delivery
G0340	Robt lin-radsurg fractx 2-5	Radiation Treatment Delivery
G6001	Echo guidance radiotherapy	Radiation Treatment Delivery (Guidance)
G6002	Stereoscopic x-ray guidance	Radiation Treatment Delivery (Guidance)
G6003	Radiation treatment delivery	Radiation Treatment Delivery
G6004	Radiation treatment delivery	Radiation Treatment Delivery
G6005	Radiation treatment delivery	Radiation Treatment Delivery
G6006	Radiation treatment delivery	Radiation Treatment Delivery
G6007	Radiation treatment delivery	Radiation Treatment Delivery
G6008	Radiation treatment delivery	Radiation Treatment Delivery
G6009	Radiation treatment delivery	Radiation Treatment Delivery
G6010	Radiation treatment delivery	Radiation Treatment Delivery
G6011	Radiation treatment delivery	Radiation Treatment Delivery
G6012	Radiation treatment delivery	Radiation Treatment Delivery
G6013	Radiation treatment delivery	Radiation Treatment Delivery
G6014	Radiation treatment delivery	Radiation Treatment Delivery
G6015	Radiation tx delivery imrt	Radiation Treatment Delivery
G6016	Delivery comp imrt	Radiation Treatment Delivery
G6017	Intrafraction track motion	Radiation Treatment Delivery (Guidance)
Q3001	Brachytherapy radioelements	Radiation Treatment Delivery (Brachytherapy Materials)
77469	Intraoperative radiation treatment management	Treatment Management