Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures

[CMS-5527-F]

Summary of Final Rule

On September 21, 2020, the Centers for Medicare & Medicaid Services (CMS) placed on public display a final rule that will 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. The final rule is scheduled to be published in the September 29, 2020 issue of the *Federal Register*. The Radiation Oncology (RO) Model provides a bundled payment for an episode of radiation therapy to treat certain types of cancer. The End-Stage Renal Disease Treatment Choices (ETC) Model makes 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 will be mandatory for eligible participants (facilities and clinicians) in selected geographic areas, and both models will begin in calendar year 2021.[1]

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

I. Overview

CMS implements 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

The 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*.[2] This report was mandated by Section 3(b) of the Patient Access and Medicare Protection Act of 2015.[3] The RO Model 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 16 cancer types that meet its model inclusion criteria including breast and prostate cancers. The payment will have professional and technical components (PC and TC, respectively), include multiple services formerly billed separately (e.g., treatment planning and

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

treatment delivery) and cover a 90-day episode of care. The RO Model transitions to a site-neutral payment on a common, adjusted national base payment amount for the episode, regardless of where it was furnished. This model is mandatory in selected geographic areas and covers about 30 percent of RO episodes of care for Medicare beneficiaries. CMS states that the model will reduce provider burden by creating a simplified, predictable payment system for RT.

B. End-Stage Renal Disease Treatment Choices Model

The ESRD ETC Model addresses the current maldistribution across renal replacement therapy options in the United States that heavily favors in-center hemodialysis. The model will test whether adjustments to existing payments to dialysis facilities and to clinicians who manage ESRD patients can increase rates of home dialysis, transplant waitlisting, and living donor kidney transplantation while lowering Medicare expenditures. Model participation is mandatory in randomly selected Hospital Referral Regions and roughly one-third of facilities, managing clinicians, and ESRD beneficiaries nationally will be involved in the model test.

From 2021 through 2023, the model will increase payments through a positive Home Dialysis Payment Adjustment (HDPA). A separate Performance Payment Adjustment (PPA), based on rates of home dialysis, transplant waitlisting, and living donor transplantation, will apply over the entire ETC Model test period. The PPA is positive or negative depending upon participant performance. To enhance fully-informed beneficiary choices of renal replacement therapy options, the ETC Model facilitates delivery of Medicare's kidney disease education (KDE) benefit by waiving certain KDE requirements. Taken together, the payment adjustments and KDE waivers are designed to substantially increase utilization of home dialysis, transplant waitlisting, and living donor kidney transplantation, versus the use of in-center hemodialysis.

C. Financial Impact

CMS estimates that the combined financial impact of the RO Model and the ETC Model will be a net federal savings of $253 million over a 5-year performance period (2021 through 2025). Of this net federal savings, $230 million is estimated to come from the RO Model and $23 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 SPECIALTY CARE MODELS			
	RADIATION ONCOLOGY (RO)	**ESRD TREATMENT CHOICES (ETC)**	**Notes**
Model start date	January 1, 2021	January 1, 2021	
Model end date	December 31, 2025 (last date during which episodes under the model must be completed). No new RO episodes may begin after October 3, 2025.	Payment adjustments end June 30, 2027	
Model category	Episode-based payment initiative	Initiative for adoption of best practices	a
Geographic unit of selection	Core-based statistical area (CBSA), randomly selected to include about 30 percent of all RO eligible episodes.	Hospital Referral Region (HRR)	
Model participation	Mandatory if selected (CMS published selected RO participating zip codes on its website). Final rule allows an opt-out for low-volume entities, defined as entities that furnishes fewer than 20 episodes in one or more of the CBSAs randomly selected for participation.	Mandatory if selected	
Participants - Clinicians	Primarily 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)	
Participant Exclusions	Excludes PGPs, Freestanding RT Centers and HOPDs in Maryland, Vermont, or U.S. Territories if it furnishes these services only in these areas. Excludes ambulatory surgery centers, critical access hospitals, or PPS-exempt cancer hospitals and those in Pennsylvania Rural Health Model. Allows an opt-out for low-volume entities (fewer than 20 episodes in a calendar year)	Clinicians and facilities in U.S. Territories, low-volume facilities and clinicians	c
Beneficiary eligibility	Fee-for-service, selected common cancer diagnoses – 16 cancer types (e.g., breast, prostate).	Fee-for-service beneficiaries age 18 or older with ESRD who reside in US. Exclusions	d

KEY FEATURES OF SPECIALTY CARE MODELS			
	RADIATION ONCOLOGY (RO)	**ESRD TREATMENT CHOICES (ETC)**	**Notes**
	Exclusions include enrollment in a MA or PACE plan, among others.	include dementia and receiving dialysis in a SNF or nursing facility.	
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	e
Minimum patient volume	Excludes low-volume RT services	Low-volume exclusions (clinician and facility) from 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-two national rates (16 for technical episodes and 16 for professional episode) adjusted for RO-participant's case mix, historical experience and geographic location. Payments are also adjusted for withholds: incomplete episodes (1 percent), quality (2 percent), and starting in PY 3, beneficiary experience (1 percent). 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 adjusted per treatment base rate) to encourage home dialysis, transplant waitlisting, and living donor transplantation: Home Dialysis Payment Adjustment (HDPA) and Performance Payment Adjustment (PPA).	
Provider Payment risk	Two-sided, applies a uniform discount factor of 3.75 percent for PC episode payments and 4.75	Two-sided for PPA. (The HDPA is a uniformly positive payment adjustment.)	h

KEY FEATURES OF SPECIALTY CARE MODELS			
	RADIATION ONCOLOGY (RO)	**ESRD TREATMENT CHOICES (ETC)**	**Notes**
	percent for TC episode payments. This is savings built into model for Medicare. Stop-loss limit of 20 percent applies for RO participants with fewer than 60 episodes.		
Quality-linked payment	Yes	No	f
Payment waivers applicable	Yes, Key waivers: Waives application of MIPS payment adjustment factors for TC 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 payment adjustments)	g
Beneficiary Cost Sharing	Twenty percent cost-sharing for each of the bundled PC and TC payments.	Twenty percent cost-sharing (no change)	h
Benefit enhancement	Expected negligible impact on the cost to beneficiaries. Incentivizes treatment plan that requires fewer services, when medically appropriate.	Increased flexibility KDE benefit, supports informed beneficiary choice of ESRD treatment options.	i
Advanced APM/MIPS APM	Yes/Yes (Expects it to qualify)	No/No	

a CMS Innovation Center model categories; the category to which the ETC Model is assigned has been inferred from the final 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 = Program of All-Inclusive Care for the Elderly; SNF = Skilled Nursing Facility
e E&M = Evaluation & Management service
f 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)
g MIPS = Merit-based Incentive Payment system (part of the QPP); APM = Alternative Payment Model; HCPCS = Healthcare Common Procedure Coding System
h TC = Technical Component; PC = Professional Component
i KDE = kidney disease education benefit; eligible beneficiary and practitioner pools expanded under ETC Model

II. General Provisions Applicable to the RO and ETC Models

A. Basis, Scope, and Definitions (§§512.100 and 512.110)

CMS observes that the Innovation Center's existing models have multiple requirements in common and proposed to apply similar requirements to both the RO and ETC Models in the proposed new 42 CFR part 512, subpart A. The proposed shared requirements (termed general provisions) would be applicable only to the RO and ETC Models, and all requirements would be applicable to both models with the exception of termination of a model participant by CMS (described further below). Each model would also have model-specific requirements. General provisions were proposed in the areas of beneficiary protections, model evaluation and monitoring, audits and record retention, rights in data and intellectual property, monitoring and compliance, remedial action, model termination by CMS, limitations on review and miscellaneous provisions on bankruptcy and other notifications. CMS notes that the provisions affecting providers and suppliers under Medicare Fee-for-Service (FFS) would be applicable to the RO and ETC Models unless specifically provided otherwise in part 512.

CMS proposed definitions for several general terms applicable under part 512.

- Model participant – an individual or entity participating in an Innovation Center model under the terms of part 512 (includes both "RO participant" and "ETC participant").
- Downstream participant - an individual or entity engaging in an Innovation Center model activity(ies) under a written agreement with a model participant.
- Innovation Center model activities - any activities impacting model beneficiary care related to the test of the Innovation Center model under the terms of part 512.
- Beneficiary – an individual enrolled in Medicare FFS.
- Model Beneficiary - beneficiary attributed to a model participant or otherwise included in an Innovation Center model under the terms of part 512.

No comments were received about the proposed basis, scope, or definitions and they are finalized without modifications.[4]

B. Beneficiary Protections

1. Freedom of Choice (§§512.110 and 512.120(a))

To protect beneficiary freedom of choice during RO and ETC Model testing, CMS proposed the following:

- Model and downstream participants must not restrict beneficiaries' abilities to choose their providers or suppliers.

[4] CMS also finalized the definition of "U.S. Territories" under part 512 to mean American Samoa, the Federated States of Micronesia, Guam, the Marshall Islands, and the Commonwealth of the Northern Mariana Islands, Palau, Puerto Rico, U.S. Minor Outlying Islands, and the U.S. Virgin Islands.

- Model and downstream participants must not commit any act or omission, nor adopt any policy that inhibits beneficiaries from exercising their freedom to choose their provider or supplier or a 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.
- "Provider" would be used as defined under section 1861(u) of the Act and codified in the definition of "provider" at §400.202, and "Supplier" would be used as defined under section 1861(d) of the Act and codified in the definition of "provider" at §400.202.

CMS received comments in support of their proposals along with requests to 1) ensure beneficiary education about the models and 2) formally solicit external feedback on beneficiary notification letters. CMS responds that 1) other provisions of the RO and ETC Models will enable appropriate beneficiary education and 2) a formal feedback process could interfere with operational timelines, but the agency will be open to informal feedback about notification content. CMS states their belief that provisions for monitoring the compliance of model participants with model terms and applicable program laws and policies (described below) will further protect beneficiaries. CMS concludes by finalizing the beneficiary protections, including the definitions of provider and supplier, as proposed.

2. Availability of Services (§§512.110 and 512.120(b))

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

- Model and downstream participants would be required to 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 ("lemon dropping").
- 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").

In response to a commenter, CMS indicates that lemon dropping and cherry-picking of beneficiaries will be identified through monitoring of model participants as described elsewhere in this rule, and through beneficiary complaints. CMS finalizes their availability of services proposals without modification. CMS had also requested comment on whether prohibiting cherry picking would prevent model participants from artificially inflating their financial or quality performance results, but received no responses.

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

To reduce the risk that payments to model participants could incent marketing behavior that would confuse or mislead beneficiaries, CMS proposed the following.

- 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.[5]
- 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.
- Model and downstream participants would be prohibited from using or distributing descriptive model materials and activities that are materially inaccurate or misleading.[6]
- 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).

A commenter requested that CMS review all marketing materials prior to their release to beneficiaries by model participants. CMS disagrees, stating their belief that reserving the right to review materials once distributed appropriately balances the risk of distribution of misleading information to beneficiaries with facilitating the release of useful information as well as limiting model participant burden. CMS also requested 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. CMS received no responses. CMS concludes by finalizing their proposals regarding availability of services without modification.

C. Model Evaluation, Monitoring and Compliance

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

Section 1115(A)(b)(4) of the Social Security Act (the Act) requires that Innovation Center model testing include evaluation of the model and public reporting of the evaluation results. Therefore, CMS proposed that RO and ETC Model and downstream participants must provide all requested

[5] General audience materials could include brochures, advertisements, outreach events, letters, web pages, mailings, and social media postings.

[6] All descriptive model materials and activities must include the 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 Medicaid Services (CMS). The authors assume responsibility for the accuracy and completeness of the information contained in this document."

information and otherwise cooperate with model evaluation activities (e.g., surveys, focus groups). CMS further proposed that those participants must comply and cooperate with other model monitoring activities as outlined at §512.150 (described below).[7] Having received no comments, CMS finalizes their proposals without modification.

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). CMS proposed that RO and ETC Model and downstream participants must comply with monitoring activities including) 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 monitoring activities, CMS or its designee would be authorized to use any relevant data or information including Medicare claims involving model beneficiaries.

CMS proposed to give 15-day advance notice of any site visit; model and downstream participants would be required to cooperate, ensuring that appropriately knowledgeable and responsible personnel are available. CMS would accommodate scheduling requests, whenever feasible. CMS also proposed to perform unannounced site visits at any time to investigate patient health and safety concerns or program integrity issues.

CMS further proposed having a "right to correct". Upon discovery of an incorrect model-specific payment, CMS may make payment to, or demand payment from, the model participant(s) involved. In lieu of proposing a deadline for payment correction, CMS requested 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).

Finally, CMS proposed 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.

A commenter stated that on-site monitoring of RO participants should be conducted by personnel and contractors with demonstrated knowledge in the specific field of radiation oncology (e.g., licensure). CMS disagrees, stating that knowledge of the RO Model and Medicare policies may be of greater import. Another commenter requested that a participant be able to request a correction(s) to a model-specific payment(s) it has received. CMS rephrases this comment as a

[7] CMS may require participants to provide protected health information and other individually identifiable data.

request for a model participant to request *reopening* of a model-specific payment determination.[8] CMS describes a reopening process and finalizes several related provisions at §512.150.

- Reopening will be permitted, whether initiated by CMS or requested by a model participant, within 4 years after the date of payment determination, for good cause.
- CMS may reopen a payment determination at any time that reliable evidence of fraud or similar fault is found to exist.
- The decision to grant or deny that a model-specific payment determination be reopened is binding and not reviewable.[9]

CMS finalizes the monitoring and compliance proposals described above, with the addition of the reopening process.

D. Audits and Record Retention (§512.135)

Model and downstream participants may receive model-specific payments, payment rule waivers, or other flexibility. CMS proposed that model-specific payments would include the home dialysis payment adjustment (HDPA) and the performance payment adjustment (PPA) of the ETC Model as well as the "participant-specific professional episode payment" and the "participant-specific technical episode payment" of the RO Model. To provide proper oversight of these payments, CMS proposed 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.

CMS also proposed to require model and downstream participants to provide access to all documents and other evidence to enable auditing by CMS of 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.

CMS further proposed 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. Were CMS to determine that a special need exists to retain a particular r record(s) for a longer period, the agency would be required to notify the participant at least 30 days before the normal retained record disposition date. When there has been a termination,

[8] CMS briefly reprises Medicare's reopening rules and refers readers to §§405.980 and 405.986.
[9] Good cause is defined at §405.986) and reliable evidence is defined at §405.902.

dispute, or allegation of fraud, records must be maintained for an additional six years from the date of final resolution.[10]

Comments were generally supportive. CMS clarifies that electronic transmission of requested materials to CMS would be considered for each audit case. CMS requested, but received no responses, as to whether record retention should be required for longer than 6 years. CMS concludes by finalizing the audit, record access, and record retention proposals without modification.

E. Remedial Action (§512.160)

CMS proposed the imposition of remedial actions on a model or downstream participant who:

- Fails to comply with any of the terms of the applicable model or with any applicable Medicare program requirement, rule, or regulation;
- Takes any action that threatens the health or safety of a beneficiary or other patient;
- Submits false data or makes false representations related to any aspect of the model;
- Undergoes a change in control that presents a program integrity risk;
- Is subject to any sanctions of an accrediting organization or a government agency;
- Is under investigation by HHS, the OIG, CMS, or the Department of Justice for alleged fraud or significant misconduct; is subject to a complaint, criminal charge, or indictment; or is a named defendant in a False Claims Act qui tam matter; or similar action; or
- Fails to improve performance following any remedial action imposed under section 512.

CMS proposed to select potential remedial actions from the following list.

- 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 as specified by CMS;
- Discontinue data sharing with the model participant;
- Recoup model-specific payments, or reduce or eliminate a model-specific payment otherwise owed to the model participant; or
- Other action(s) as may be permitted under the terms of part 512.

For the ETC Model only, CMS proposed the potential action of terminating a participant from the model if the participant engages in egregious actions. CMS did not propose such a provision

[10] Model participants would be required to notify their downstream participants should CMS identify a special record retention need or undertake termination, dispute, or allegation of fraud or similar fault involving the model or downstream participant(s).

for the RO Model, whose provider and supplier types are thought to represent a lower risk of fraud and abuse than that historically present in the dialysis industry.

CMS received no comments on their remedial action proposals and finalizes them unchanged.

F. Limitations on Review (§512.170)

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

- Selection of models for testing or expansion under section 1115A of the Act;
- Selection of organizations, sites, or participants for model testing, including any CMS decision to remove a model participant or require removal of a downstream participant;
- Elements, parameters, scope, and duration of models for testing or dissemination;
    - Selection of quality performance standards for the model by CMS.
    - Assessment by CMS of the quality of care furnished by the model participant.
    - Attribution of model beneficiaries to the model participant by CMS, if applicable.
- Determinations regarding budget neutrality under section 1115A(b)(3) of the Act;
- Termination or modification of the design and implementation of a model under section 1115A(b)(3)(B) of the Act; and
- Determinations about expansion of a model's duration and scope under section 1115A(c) of the Act, including failure to meet the criteria in paragraph (1) or (2) of the section.

CMS responds to a comment by clarifying that the limitations on review apply to the methodology for assessing quality of care, and agrees that a participant should be allowed to challenge an adverse assessment of the actual care provided. CMS finalizes their proposals on review of limitations with modification to allow challenges of adverse care quality assessments.

G. Other Provisions

1. <u>Data and Intellectual Property Rights (§512.140)</u>

CMS proposed that information obtained in accordance with §§512.130 and 512.135 may be used to evaluate and monitor the RO and ETC Models. CMS also proposed that qualitative and quantitative results may be disseminated to other providers and suppliers and to the public, including de-identified results calculated based upon claims, medical records, and other data sources. CMS further proposed that model or downstream participants may request that CMS protect proprietary or confidential information submitted to CMS, if identifiable as proprietary or confidential and confirmed as such by CMS. Finally, CMS proposed not to release confirmed proprietary or confidential information without the expressed consent of the model or downstream participant, unless release is required by law. CMS notes receiving no comments and finalizes their proposals without modification.

2. Model Termination by CMS (§512.165)

Reasons proposed by CMS for termination of the RO and/or ETC Models included lack of CMS funding for the model and failure to meet criteria for model expansion under section 1115A(c) of the Act.[11] CMS also proposed to notify model participants in writing about termination, including the effective date of and grounds for termination. CMS notes receiving no comments and finalizes their proposals without modification.

3. Bankruptcy and Related Notifications (§512.180)

CMS proposed that model participants notify CMS of events that could impact their ability to meet their financial obligations under the model.

- A participant filing a bankruptcy petition must provide written notice to CMS and to the local U.S. Attorney's Office by certified mail within 5 days of filing the petition.
- 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.
- A model participant must provide written notice to CMS at least 90 days before the effective date of any change in control (e.g., an agreement for the sale or liquidation of the model participant).

CMS also proposed that a change in control could precipitate immediate reconciliation and demand for repayment of all monies owed to CMS. The participant also could be subject to remedial action should the change in control create a Medicare program integrity risk.

Commenters asked that, to reduce provider burden, the period for reporting a legal name change be revised from 60 days before to 30 days after the effective date of the name change. CMS agrees and finalizes all of their proposals with the revised name change reporting timeline.

[11] 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.

III. Radiation Oncology Model

A. Introduction

CMS establishes in this final rule a mandatory Radiation Oncology Model (RO Model) to test whether prospective episode-based payments for radiotherapy or radiation therapy (RT) services will reduce Medicare program expenditures and preserve or enhance quality of care. This model will be mandatory in selected geographic areas. Under this model, Medicare will 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 will be the same for hospital outpatient departments (HOPDs) and freestanding radiation therapy centers. The performance period will be for five performance years (PYs) beginning in January 2021.

The following policies for the RO Model are discussed in the final 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 final 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[12, 13] and is typically furnished by a radiation oncologist. As discussed in the proposed rule, 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 showed that HOPDs furnished 64 percent of episodes nationally, while freestanding radiation therapy centers furnished the remaining 36 percent of episodes.[14] 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 stated that it does not appear that a clinical rationale explains the difference in resource costs, although it observed that freestanding radiation therapy centers

[12] Physician Characteristics and Distribution in the U.5., 2010 Edition, 2004 IMV Medical Information Division, 2003 SROA Benchmarking Survey.
[13] Radiation Therapy Benchmark Report, IMV Medical Information Division, Inc. (2013).
[14] CMS made 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/

use more IMRT, which is associated with higher Medicare payments.

CMS noted 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 does not allow flexibility to test new value-based payment approaches.

CMS cited 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 stated 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 proposed what the Innovation Center determined to be the best design for testing an episodic APM for RT services.

Comments/Responses: Most commenters supported most aspects of the proposed RO Model and expressed their commitment to fully participating in a value-based care model. Several commenters raised concerns about the lack of telehealth discussion in the RO Model. Others were more critical of the RO Model requesting that the site neutral payment policy be abandoned and that CMS does not have the statutory authority to implement site-neutral payments and is using section 1115A to adopt a policy preference that CMS otherwise could not adopt. Commenters raised many other concerns, many of which are addressed in the relevant sections below.

CMS in response appreciates commenters' support in its efforts to move forward with the RO Model and is finalizing most aspects of the model, as discussed further below. For telehealth, CMS notes that there are no permanent Medicare telehealth codes included in the list of included RT services in its RO Model. HCPCS code 77427 has been temporarily added to the list of Medicare telehealth codes for the PHE for the COVID-19 pandemic. CMS is taking this comment into consideration for future rulemaking. With respect to site-neutral payments, CMS believes that the observed differences between HOPDs and freestanding radiation therapy centers are unwarranted because the actual treatment and care received by patients for a given modality is the same in each setting. With respect to its authority to implement this RO Model, CMS disagrees with the commenter and believes that section 1115A of the Social Security Act gives the Secretary the necessary authority to conduct the RO Model.

C. RO Model Regulations

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

1. Model Performance Period

CMS proposed 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 proposed "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.

Comments/Responses: Almost all the commenters were opposed to the RO Model beginning on January 1, 2020 and many believed that even the alternative suggested date of April 2020 was insufficient to prepare. CMS notes in its response that it had intended to start the RO Model on July 1, 2020, but as it was completing the final rule, the U.S. began responding to the COVID-19 virus, which was declared a Public Health Emergency (PHE). In light of this unprecedented PHE, CMS finalizes the RO Model performance period to begin on January 1, 2021 as it believes that RO participants may have limited capacity to meet the RO Model requirements in 2020.

Other commenters expressed specific concerns RO participants would face considerable administrative burden and would not have sufficient time to plan for implementation. These concerns included the need for electronic health records (EHR) vendors to have ample time to design, develop, build, test, validate, and implement the software in their respective EHR platforms, and that RO participants would have insufficient time to operationalize the RO Model's coding and billing requirements. In response, CMS notes that it believes that RO participants and its EHR vendors will have sufficient time to meet these requirements.

Final Decision: CMS finalizes its proposed RO Model performance period at §512.205, with the modification that the five-year performance period will begin on January 1, 2021 and end on December 31, 2025. Each PY will consist of a 12-month period beginning on January 1 and

ending on December 31st. For all episodes to be completed by December 31, 2025, CMS finalizes that no new RO episodes may begin after October 3, 2025.

2. Definitions

CMS defines at §512.205 certain terms of the RO Model. These definitions are described through section III of the final rule and any comments CMS received are described in its respective section.

3. Participants

In this section, CMS describes its policies 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. Required Participation

CMS proposed 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 model is necessary to develop a robust data set for evaluation of this prospective payment approach.

Comments/Responses: Most commenters were generally opposed to proposed mandatory participation in the model. Many suggested that participation in the model be voluntary, or that participants have the option to opt-in or opt-out. Others suggested that the RO Model have a "phase-in" period for participants such that the model would begin as voluntary and transition to mandatory participation in subsequent years. For example, one commenter recommended voluntary participation for the initial two of five performance years, and then phase-in mandatory participation over the remaining 3-year period. Another commenter recommended testing multiple small-scale voluntary models with differing payment methodologies simultaneously to determine which approach would have the greatest impact with the fewest unintended consequences.

In response, CMS expresses its belief that it would be unable to accurately evaluate the RO Model if the model was voluntary for all RT providers and RT suppliers or had a phased-in approach. It believes that such a voluntary approach would result in selection bias as only those providers expected to be successful would opt-in and thus hindering a robust evaluation. At the same time, CMS states it recognizes that certain practices under the RO Model may face potential financial hardship, particularly those that are low volume. It modifies its proposed policy to include an opt-out option for RT providers and RT suppliers that are low volume (see section II.C.3.e of this final rule summary for additional information).

Other commenters questioned CMS' statutory authority to implement the RO Model using section 1115A of the Act. Some questioned the proposal requiring mandatory participation of approximately 40 percent of radiation oncology episodes as they believed this represents a major policy change, and not a test of payment and service delivery models. CMS rejects this argument and believes that it has the legal authority consistent with section 1115A of the Act to require the participation of all RT providers and RT suppliers. It also notes that the RO Model will not be the first Innovation Center model that requires participation citing the Comprehensive Care for Joint Replacement (CJR) Payment Model.

Final Decision: After considering public comments, CMS finalizes its proposal for mandatory participation with modification. It codifies at §512.210(a) that any Medicare-enrolled Physician Group Practice (PGP), freestanding radiation therapy center, or HOPD, unless otherwise specified at §512.210(b) or (c), that furnishes included RT services in a 5-digit ZIP Code linked to a CBSA selected for participation to an RO beneficiary for an RO episode that begins on or after January 1, 2021, and ends on or before December 31, 2025, must participate in the RO Model. Taking into account concerns raised by commenters, CMS finalizes required participation for all RT providers and RT suppliers located within the CBSAs selected for participation, with the modification that the model size will be reduced to approximately 30 percent of eligible episodes in eligible CBSAs (see section III.C.5 of this final rule summary), and with an inclusion of a low volume opt-out for any PGP, freestanding radiation therapy center, or HOPD that furnishes fewer than 20 episodes in one or more of the CBSAs randomly selected for participation in the most recent year with claims data available (see section III.C.3.c of this final rule summary).

b. RO Model Participants

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

Term	**Definition**
RO participant	Medicare-enrolled physician group practice (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), and all 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 definition of a PC is the included RT services that may only be furnished by a physician. The 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. RO Model Participant Exclusions

CMS proposed 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. CMS argued that 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 proposed 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 clarified 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 in location to a CBSA selected for participation 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 proposed to codify these policies at §512.210 of its regulations.

Comments/Responses: Commenters were generally supportive of the exclusions CMS proposed from the RO Model, but many suggested other exclusions. These suggestions included sole community hospitals (SCH), Medicare dependent hospitals (MDH), or allowing participants that are low volume the option to opt out of the RO Model. One commenter noted that provider and suppliers who furnished fewer than 60 attributed episodes during the 2015-2017 period found considerable variation in episode spending suggesting that episode pricing would be highly random and difficult for them to manage. Other suggested that low-volume providers and suppliers would face administrative, financial, and infrastructure challenges.

Final Decision: In its response, CMS acknowledges the general support for its exclusions,[15] and finalizes it proposals with one modification to allow an opt-out for low-volume entities, which it codifies at §512.210(c). This option allows any PGP, freestanding radiation therapy center, or HOPD to opt-out of the RO Model, if in the most recent calendar year with episode data available, the entity furnishes fewer than 20 episodes in one or more of the CBSAs randomly selected for participation. CMS notes that its most recent analysis of claims data indicates that 20 episodes is an appropriate threshold. It also notes that while some commenters suggested using the MIPS low-volume threshold, CMS note that this is not a feasible option as this would result in a nearly 50 percent reduction in the number of RO participants and would not allow for a statistically valid RO Model evaluation or generate sufficient savings.

d. Geographic Unit of Selection

CMS proposed that the geographic unit of selection for the RO Model would be the Office of Management and Budget (OMB) CBSA. 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).[16] CMS stated that it chose CBSAs as the proposed geographic unit of selection as they are ideal for use in statistical analyses because there are 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 not be required to participate in the model.

CMS proposed 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 noted, 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

[15] CMS clarifies how it will identify specific HOPDs that are excluded from participation in the RO Model because of their participation in the Pennsylvania Rural Health Model.[15] CMS will use the list (updated quarterly) on the Pennsylvania Rural Health Model's website at https://innovation.cms.gov/initiatives/pa-rural-health-model/.

[16] CBSAs are defined by OMB and published on Census.gov

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 proposed 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. 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. CMS believed 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[17] to link each five-digit ZIP Code to a single CBSA. If finalized, CMS stated 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 proposed 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 stated 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 did 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.

Comments/Responses: Many commenters were opposed to the proposed size of the RO Model to include 40 percent of all eligible episodes and suggested a reduction in the size of the model that ranged from 7 percent to 25 percent of all eligible episodes. Other commenters expressed concern that the use of CBSAs to identify RO participants could result in unintended consequences, such as picking "winners and losers" in markets as this model could provide incentives for patients to travel based on RT provider or supplier participation in the model. A few commenters encouraged CMS to allow public comment on the particular CBSAs for participation in the RO Model.

In its response, CMS agrees, in part, with commenters about the scale of the RO Model, and finalizes the proposed scope of the model at §512.210(d) with modification to reflect a reduced scale to approximately 30 percent of the eligible episodes (down from 40 percent from the

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

proposed rule). CMS notes that its decision is supported by additional power calculations that incorporated episode data from 2016-2018 FFS claims data not available at the time of the proposed rule.

With regards to CBSAs being chosen as the geographic unit of selection, CMS notes that CBSAs as proxies for these markets will achieve a reasonable balance among the tradeoffs raised by commenters. CMS also acknowledges that the model could potentially result in health systems having both RO participants and non-participants and could result in additional burden for these systems in terms of billing and the ability to manage patients. It notes for clarification that episodes are assigned to a single CBSA by way of the Zip Code of the RT supplier that furnished the planning service that triggered the RO episode. CMS also stresses that its supports Medicare patients' rights to seek care wherever they choose, but doesn't believe that its model would justify or lead to beneficiaries traveling to entirely different CBSAs to seek RO care, given the nature of the treatment which requires frequent treatments over a short period.

CMS states it will also provide a look-up tool that includes all the five-digit ZIP Codes linked to CBSAs selected for participation in accordance with its finalized selection process. This tool can be found at its RO Model website (https://innovation.cms.gov/innovation-models/radiation-oncology-model), and will allow entities that furnish RT services to identify if they are included or excluded from the RO Model based on their site of service.

CMS has not yet published the CBSAs associated with these ZIP Codes. Using the CMS data, we estimated the top 20 CBSAs (based on participating ZIP Codes) in the table below as an illustration of its scope. Potential participants should verify the RO Model website to check whether their ZIP Code is included in the model; this is particularly true for ZIP Codes that are part of multiple CBSAs given how CMS assigns those ZIP Codes, as described above.

Top 20 CBSAs (based on participating ZIP Codes) Chosen to Participate in Model

CBSA	CBSA Name
47900	Washington-Arlington-Alexandria, DC-VA-MD-WV
37980	Philadelphia-Camden-Wilmington, PA-NJ-DE-MD
38300	Pittsburgh, PA
14460	Boston-Cambridge-Newton, MA-NH
26420	Houston-The Woodlands-Sugar Land, TX
33100	Miami-Fort Lauderdale-Pompano Beach, FL
19820	Detroit-Warren-Dearborn, MI
45300	Tampa-St. Petersburg-Clearwater, FL
41700	San Antonio-New Braunfels, TX
10580	Albany-Schenectady-Troy, NY
18140	Columbus, OH
36540	Omaha-Council Bluffs, NE-IA
39300	Providence-Warwick, RI-MA
32820	Memphis, TN-MS-AR

CBSA	CBSA Name
40060	Richmond, VA
29820	Las Vegas-Henderson-Paradise, NV
37900	Peoria, IL
45060	Syracuse, NY
23420	Fresno, CA
39100	Poughkeepsie-Newburgh-Middletown, NY

Source: Estimated based on CMS Participating Zip Codes and Zip Code/CBSA files

Final Decision: CMS finalizes with modification its proposed provisions on the RO Model's geographic unit of selection. Specifically, CMS codifies at §512.210(d) that it will randomly select CBSAs to identify RT providers and RT suppliers to participate in the RO Model through a stratified sample design. It finalizes that approximately 30 percent of eligible episodes will be randomly selected for this model. CMS will use Medicare FFS claims from January 1, 2016 through December 31, 2018 for constructing episodes, determining sufficient sample size, and for the eventual selection of participants and comparators for the RO Model, as this was the timeliest data available at the time of this final rule's release.

4. Beneficiary Population

CMS proposed that a Medicare FFS beneficiary be included 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 proposed to exclude 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 proposed these criteria 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 its proposal, a beneficiary who met all these criteria, and who does not trigger any of the beneficiary exclusion criteria, would be called a "RO beneficiary". CMS proposed to codify the terms "RO beneficiary," "RT provider," and "RT supplier" at §512.205.

In addition, CMS proposed 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 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.

Comments/Responses: A few commenters requested that all patients enrolled in clinical trials be excluded from the RO Model. Others suggested that CMS should open the RO Model to voluntary participation by Medicare Advantage plans and other payers. Several commenters sought clarification on various issues.

With respect to exclusion of enrolled clinical trial patients form the RO Model, CMS notes that it pays routine costs by way of FFS payment for Medicare beneficiaries participating in clinical trials when there exists a benefit category. It argues that not including clinical trials that are paid through FFS could skew the model results. CMS notes that it does not plan to open the RO Model to voluntary participation by Medicare Advantage plans and other payers as its model was designed to test an alternative payment approach instead of FFS. CMS clarifies that if a patient starts an episode with inpatient treatment and then changes to an outpatient setting, this situation would not be considered an RO episode, and treatment would be billed under traditional fee-for-service. If a patient changes Zip Codes during treatment, CMS notes that Zip Codes are relevant only to the location of the RO participant, not the residence of the beneficiary.

Final Decision: After considering public comments, CMS finalizes its proposal on the beneficiary population with modification. It made additional non-substantive changes to its proposed provisions at §512.215 in this final rule to improve readability. Specifically, CMS finalizes, with modification, the RO Model beneficiary inclusion criteria as codified at §512.215(a) and illustrated in Figure A (reproduced below).

Figure A: Finalized RO Beneficiary Inclusion Criteria

The individual receives included RT services: • from an RO participant that billed the Start of Episode (SOE) modifier for the PC or TC of an RO episode during the Model performance period for an included cancer type
At the time that the initial treatment planning service of the RO episode is furnished by an RO participant, the individual: • Is eligible for Medicare Part A and enrolled in Medicare Part B • Has traditional Medicare FFS as his or her primary payer (for example, is not enrolled in a PACE plan, Medicare Advantage or another managed care plan, or United Mine Workers insurance) • Is not in a Medicare hospice benefit period

Additionally, CMS finalizes as proposed to codify the terms "RT provider," and "RT supplier" at §512.205. It finalizes, with modification, to codify the term "RO beneficiary" at §512.205 to mean a Medicare beneficiary who meets all of the beneficiary inclusion criteria at §512.215(a) and whose RO episode meets all of the criteria defined at §512.245. As explained in the

proposed rule and in this final rule, the RO Model's design would not allow RO beneficiaries to "opt out" of the Model's pricing methodology.

5. RO Model Episodes

Under the RO Model, Medicare will 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 and its finalized policies 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 and its finalized policies for the conditions that must be met to trigger a 90-day episode.

a. Included Cancer Types

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

CMS identified 17 cancer types that met 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.

CMS stated that it would maintain the list of ICD-10 codes for included cancer types under the RO Model on the RO Model website. 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.

Comments/Responses: Many commenters expressed concern over certain cancers being included as part of the list including kidney, cervical and liver cancers. For cervical cancer, a commenter

called into question the data used to determine the national base rates for cervical cancer, stating that the payment methodology is not well-suited for cancers commonly treated with multiple modalities. Other commenters suggested that a subset of cancer types should be included such as the most prevalent cancer types: breast, colon, lung, and prostate as these cancers are more homogeneous and their costs are more predictable.

CMS in its response reconsidered the inclusion of kidney cancer and now believes based on further clinical review that it does not meet the criteria for inclusion. It is not commonly treated with radiotherapy and may have been included initially as artifact of inaccurate coding. CMS was not convinced that liver and cervical or other cancers should be excluded.

Final Decision: CMS finalizes 16 cancer types for inclusion in the RO Model as cancers commonly treated with RT. This list is described in Table 1 of the final rule along with the list of ICD-10 codes (reproduced below). It finalizes without change, its proposed criteria for included cancer types and for removing cancer types at §512.230(a) and (b) of its regulations. Additionally, CMS finalizes without change at §512.230(c) its proposal to notify RO participants of any changes to the diagnosis codes for the included cancer types by displaying them on the RO Model website no later than 30 days prior to each performance year.

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

Cancer Type	ICD-10 Codes
Anal Cancer	C21.xx
Bladder Cancer	C67.xx
Bone Metastases	C79.5x
Brain Metastases	C79.3x
Breast Cancer	C50.xx, D05.xx
Cervical Cancer	C53.xx
CNS Tumors	C70.xx, C71.xx, C72.xx
Colorectal Cancer	C18.xx, C19.xx, C20.xx
Head and Neck Cancer	C00.xx, C01.xx, C02.xx, C03.xx, C04.xx, C05.xx, C06.xx, C07.xx, C08.xx, C09.xx, C10.xx, C11.xx, C12.xx, C13.xx, C14.xx, C30.xx, C31.xx, C32.xx, C76.0x
Liver Cancer	C22.xx, C23.xx, C24.xx
Lung Cancer	C33.xx, C34.xx, C39.xx, C45.xx
Lymphoma	C81.xx, C82.xx, C83.xx, C84.xx, C85.xx, C86.xx, C88.xx, C91.4x
Pancreatic Cancer	C25.xx
Prostate Cancer	C61.xx
Upper GI Cancer	C15.xx, C16.xx, C17.xx

Cancer Type	ICD-10 Codes
Uterine Cancer	C54.xx, C55.xx

b. Episode Length and Trigger

CMS proposed that the length of an episode under the RO Model would 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 proposed 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.

As part of its proposal, CMS stated that 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 would inform the Technical participant of when the episode began.

CMS proposed 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 referred 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 proposed 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 stated 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.

Comments/Responses: Some commenters expressed a concern that the 90-day episode period would incentivize providers and suppliers to reduce the number of fractions into the shortest possible course of treatment. Many also expressed concern that the 90-day episode period is not

sufficiently responsive to patients whose cancer might recur, metastasize, require multiple treatment modalities, or otherwise require additional treatments within the 90-day period. A few commenters expressed concern about the 28-day episode trigger window stating that in certain situations such as cases requiring multi-radiation modalities, coordination with other specialties might make it difficult to deliver treatment within that timeframe.

In response, CMS notes that its data show that treatment almost always occurs within this period, and if it does not, this would constitute an incomplete episode.

Final Decision: CMS finalizes at §512.205, as proposed, the definition of RO episode. CMS also finalizes as proposed its incomplete episode policy. In addition, CMS finalizes as proposed at §512.245(c) that an episode must not be initiated for the same RO beneficiary during a clean period.

c. Included RT Services

CMS proposed 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 proposed 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 proposed 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.

Term	Definition
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 did not propose 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 proposed 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 proposed 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 proposed 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 the final list is reproduced in the Appendix at the end of this summary).

CMS proposed 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.

Comments/Responses: Commenters noted concerns about certain services including radiopharmaceuticals, brachytherapy sources and surface guided radiation therapy (SGRT). In the cases of radiopharmaceuticals, commenters noted that certain treatments, as with the case of Radium, often occur monthly for six months, far longer than the 90-day episode. With respect to brachytherapy sources, many were concerned that the model would not appropriately compensate for differences in isotopes and radioactive intensity. Commenters had a similar concern with SGRT (code 77387 and G6017) and point out to CMS that it has not established PFS payment for the G6017 code and recommend that CMS pay for this separately from the model. Many commenters also expressed an overall concern about the lack of consideration for emerging or new technologies in the RO Model.

CMS replies that as indicated in the proposed rule radiopharmaceutical are excluded from the RO Model and it mistakenly included C2616 in the proposed rule list and is now removing it from the list of RO Model Bundled HCPCS. It disagrees that brachytherapy sources will not be adequately compensated in the model, and believes that once the national base rates are adjusted for the RO participant's case mix and historical experience, final payments should be reflective of the inclusion of radioelements. CMS agrees with commenters that CPT code 77387 should not be include in the model as it is not paid separately. It clarifies that code G6017 is contractor-priced under the PFS, and as such CMS will use the payment amounts determined by the individual MACs in the calculation of national base rates. For new technologies and new equipment billed under new HCPCS codes, CMS states that it would go through rulemaking to add these new codes to the list of RO Model Bundled HCPCS list. These codes would be paid under FFS until they were added to the bundled HCPCS list.

Final Decision: CMS modifies its proposed list of included RT services to the corresponding HCPCS codes in Table 2 of this final rule (reproduced in the Appendix at the end of this summary). It is not adding any HCPCS codes to those identified in the proposed rule, but removes HCPCS codes 77387, 77424, 77425, C1715, C1728, C2616, and 77469 from the Model. CMS codifies at §512.235 that only the following RT services furnished using an included modality identified at §512.240 for an included cancer type are included RT services that are paid for by CMS under §512.265: (1) treatment planning; (2) technical preparation and special services; (3) treatment delivery; and, (4) treatment management; and at §512.270 that these RT services would not be paid separately during an episode. All other RT services furnished by an RO participant during the Model performance period will be subject to Medicare FFS payment rules.

d. Included Modalities

CMS proposed 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.

Comments/Responses: Many commenters believed that PBT is of high value and an effective evidence-based treatment for many clinical indications. They argued, in part, that while PBT is more expensive up-front, it has significant long-term benefits and savings that may not be captured within the 90-day episode and should not be included in the Model. A majority of commenters also opposed inclusion of brachytherapy in the RO Model and were concerned that the RO Model would not provide adequate payment for all situations in which brachytherapy is indicated, particularly when a single episode involves multiple treatment modalities. One commenter suggested that IORT should be excluded from the model as it will promote the use of short course, less costly forms of treatment where traditional external beam radiation would have been preferred.

CMS notes that it is finalizing as proposed the inclusion of PBT in the RO Model with the exception of when PBT is furnished to an RO beneficiary participating in a federally-funded, multi-institution, randomized control clinical trial for PBT so that further clinical evidence

assessing its health benefit comparable to other modalities can be gathered. CMS disagrees with excluding brachytherapy from the model and believes that national base rates are based on the notion of averages and will include situations where multiple modalities are used. CMS states that it will monitor for changes in treatment patterns and will consider modifications to the pricing methodology in future years should it be warranted. It agrees with the commenter that IORT should be excluded from the model because it is not a standard approach to treatment and may incentivize misuse of this treatment.

Final Decision: CMS finalizes its proposed list of included modalities in the RO Model at §512.240, with the modifications of removing intraoperative radiotherapy (IORT) from the list of included modalities in the RO Model.

6. 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 defines 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 pricing methodology (changes from the proposed rule to the final are discussed in each of the sections below). CMS makes one technical change to apply the geographic adjustment to the trended national base rates prior to the case mix and historical experience adjustments and prior to the discount factor and withholds. The steps below reflect those changes.

Step 1	Create a set of national base rates for the PC and TC of the included cancer types, yielding 32 different national base rates (i.e., historical average cost)
Step 2	Apply a trend factor to the 32 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	Apply geographic adjustments to the trended national base rates
Step 4	Adjust the 32 national base rates after the trend factor and geographic adjustments to account for each RO Participant's case-mix and historical experience. Case-mix and historical experience adjustments may not apply for RO participants that have fewer than 60 episodes.
Step 5	Adjust payment by applying a discount factor to reserve savings for Medicare and reduce beneficiary cost-sharing. Discount factor for the PC is 3.75 percent and for the TC is 4.75 percent.

Step 6	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 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 defines the term "duplicate RT service" (at §512.205) to mean any included RT service that is furnished to an RO beneficiary by an RT provider or RT supplier that is not excluded from participation in the RO Model at §512.210(b), and that did not initiate the PC or TC of the RO beneficiary's RO episode.

CMS also includes its definition of an "incomplete episode" in this section. An incomplete episodes is defined as an episode that is deemed not to have occurred because: (1) a Technical participant or a Dual participant does not furnish a technical component to an RO beneficiary within 28 days following a Professional participant or the Dual participant furnishing an initial treatment planning service to that RO beneficiary; (2) an RO beneficiary ceases to have traditional FFS Medicare as his or her primary payer at any time after the initial treatment planning service is furnished and before the date of service on a claim with an RO Model-specific HCPCS code and an end of episode (EOE) modifier; or (3) an RO beneficiary switches RT provider or RT supplier before all included RT services in the RO episode have been furnished.

Each is described in more detail below.

Comments/Responses: CMS received many overall comments on its pricing approach with many expressing support for the prospective payment model and others expressing concern about the prospective nature of the model's payment rates. Others were concerned that the RO Model provided no safeguard for excessive downside financial risk and suggested that the RO Model take a "shared savings" approach with RO participants sharing risk for gains/losses. Commenters also requested clarity on whether episode payment amounts covered all RT services furnished during a 90-day period, even in instances where multiple courses of treatment were furnished. Detailed comments on certain aspects of the pricing approach are discussed in each of the sections below.

In its response, CMS states that the prospective episode-based payment structure is the best design for testing an episodic APM for RT services. The payment rates are unambiguous and known to RO participants prior to furnishing RT services, which allows it to test the impact of episode-based payments that do not include today's FFS incentives, which encourages more utilization than is perhaps necessary. CMS believes its methodology is sufficient to account for differences in beneficiary characteristics that could have a large impact on episode payments and is also designed to account for what each participant has been paid historically under FFS. It does not believe additional protections are needed, except for RO participants that have fewer

than 60 episodes in the baseline period as they might not have enough historical volume to reliably calculate certain adjustments. CMS is adopting additional safeguards for these RO participants (discussed in section III.C.6.e(4) of the final rule and summary).

CMS clarifies that episode payment amounts cover all RT services even when multiple courses of treatment are provided. An RO episode includes all included RT services (see Table 2 in final rule and reproduced in Appendix of summary) furnished to an RO beneficiary with an included cancer type during the 90-day episode. If an RO episode includes RT services for different included cancer types, those RT services and their costs and are included in the calculation of the payment rate for that episode. CMS provides additional detail on its approach on pages 231-233 of the display copy.

Final Decision: CMS generally finalizes its overall pricing approach but does incorporate some modifications based on the comments received. These are discussed in more detail below and listed here.

(1) Changes the name of the "efficiency factor" of the historical experience adjustment to "blend."
(2) Reduces the discount rate of the PC and TC from 4 and 5 percent to 3.75 and 4.75 percent, respectively.
(3) Reduces the incorrect payment withhold from 2 percent to 1 percent.
(4) Applies a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes during 2016-2018 and that were furnishing included RT services in the CBSAs selected for participation at the time of the effective date of the final rule.

CMS also makes the following modifications, which are not being codified in regulation text, to its pricing methodology policy:

(1) Changes the baseline from which the national base rates, Winsorization thresholds, case mix coefficients, case mix values, and historical experience adjustments are derived from 2015-2017 to 2016-2018.
(2) Changes the sequence of the proposed eight primary steps to the pricing methodology, that is apply the geographic adjustment to the trended national base rates prior to the case mix and historical experience adjustments and prior to the discount factor and withholds.
(3) Updates the years used in the trend factor's numerator and denominator calculation. For the trend factor's numerator calculation, the most recent calendar year with complete data used to determine the average number of times each HCPCS code was furnished will be 2018 for PY1, 2019 for PY2, and so forth. The trend factor's denominator calculation will use data from 2018.
(4) Updates the years used to determine the case mix values, beginning with 2016-2018 for PY1, 2017-2019 for PY2, and so on.
(5) Aligns the approach to deriving expected payment amounts for each episode in the case mix adjustment with how the predicted payment amounts are calculated by using regression models for both calculations; for the expected payment amounts, the regression model would be a simple one that contains cancer type only on the right

hand side rather than using the average Winsorized baseline expenditures by cancer type).

(6) Updates the years used to determine whether an HOPD or freestanding radiation therapy center has fewer than 60 episodes, making them ineligible to receive a historical experience adjustment, from 2015-2017 to 2016-2018 to mirror the change in baseline noted in (1).

(7) Updates the years used to determine whether an HOPD or freestanding radiation therapy center has fewer than 60 episodes, making them ineligible to receive case mix adjustment, beginning with 2016-2018 for PY1, 2017-2019 for PY2, and so on.

(8) Updates the episodes used to determine the RVU shares of the PFS geographic adjustment from 2015-2017 episodes to 2018 episodes.

b. Construction of Episodes using Medicare FFS Claims and Calculation of Episode Payments

CMS proposed 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.

CMS proposed 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 clarified in the proposed rule 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.\

Comments/Responses: A few commenters disagreed with weighting the most recent episodes more heavily than those in the earlier years, as the 2017 rates were the lowest rates of all three years in the baseline. CMS in response states that it gave more weight to the most recent years because this reflects the most recent treatment patterns, not because they are the "lowest" rates.

Final Decision: CMS finalizes this provision with modification to construct episodes based on dates of service for Medicare FFS claims paid during the CYs 2016-2018. CMS will weight episodes that initiated in 2016 at 20 percent, episodes that initiated in 2017 at 30 percent, and episodes that initiated in 2018 at 50 percent.

c. National Base Rates

CMS proposed 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 proposed 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. In the proposed rule CMS states that 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.

As stated in the proposed rule, CMS would exclude 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 proposed 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 proposed 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 concluded 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. CMS stated 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 stated 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 and included 32 national base rates (16 PC rates and 16 TC rates).

Comments/Responses: CMS received numerous comments on its approach calculating the national base rates and key highlights are summarized. Many commenters disagreed with the proposal for calculating the national base rates based on an average payment of episodes from only the HOPD setting as it does not reflect the actual payment experience for freestanding radiation therapy centers. These commenters also recommended calculating the national base rates using a blend of PFS and OPPS rates rather than basing the rates on OPPS rates alone, and several commenters also recommended using more recent data than 2015-2017, if available. Among other suggestions, several commenters suggested CMS establish tiered base

rates rather than a single base rate per cancer type. Commenters also suggested that data integrity is challenged by the ICD-9 and ICD-10 diagnosis coding. Several commenters disagreed with the proposal to provide each RO participant its participant-specific professional episode payment and/or its participant specific technical episode payment 30 days before the start of the PY. These commenters proposed a 60-day notice period or a 90-day notice like notice given to participants of the CJR model.

CMS responds to concerns about using HOPD data by referring readers to the November 2017 Report to Congress that discusses FFS incentives and the site-of-service payment differentials between HOPDs and freestanding radiation therapy centers. CMS believes that OPPS data have a stronger empirical foundation than PFS rates as OPPS rates are constructed from hospital cost report data. It does not believe a blend of PFS and OPPS rates would be preferrable as its has found no evidence supporting different utilization rates based on different settings. It clarifies that although the national base rates in the RO Model are calculated based on episodes occurring in the HOPD setting, these episodes include payments made to physicians under the PFS for the PC and payments to freestanding radiation therapy centers for the TC include episodes where beneficiaries sought treatment from both HOPDs and freestanding radiation therapy centers. It agrees with commenters about using more recent baseline data, and therefore, it is finalizing the calculation of national base rates based on HOPD data as proposed with modification to change the baseline from 2015-2017 to 2016-2018. This transition also reduces the risk of coding errors that could result from the transition from ICD-9 to ICD-10 codes as 2016-2018 claims data use ICD-10 coding.

With respect to establishing tiered base rates rather than a single base rate per cancer type, CMS has only claims data available to design and operationalize the RO Model, and thus does not have the clinical or resource level data to design tiered based rates. It also believes that its case-mix adjustment and the historical experience adjustments should accurately capture differences in RO participants' patient populations.

CMS states that it is not feasible for it to provide much more than 30-day notice to provide participant-specific professional and technical episode payment to RO participants. Information needed by CMS to perform certain calculations is dependent upon publication of the PFS and OPPS final payment rules for the upcoming calendar year—these rules are statutorily required to be 60 days in advance of the start of the calendar year. To the extent that it is feasible, CMS states that is will notify RO participants of these adjustments prior to the 30-day notice.

CMS also notes one technical, but significant, change in the information that it will provide. It will provide each RO participant its case mix and historical experience adjustments for both the PC and TC in advance of the PY, rather than their participant-specific professional and technical episode payment amounts, because exact figures for the participant-specific professional and technical episode payment amounts cannot be known prior to claims processing for several reasons. These reasons include differences in the application of the geographic adjustment, rounding differences between steps, payment adjustments due under MIPS, and changes to

Medicare payments based on situations where the beneficiary coinsurance is capped at the inpatient deductible limit under OPPS.

Final Decision: CMS finalizes as proposed the determination of national base rate as codified at §512.250. It finalizes its proposal with one technical change. It is modifying the regulatory text at §512.255 to specify that 30 days before the start of each performance year, CMS will provide each RO participant its case mix and historical experience adjustments for both the professional and technical components. It also finalizes the calculation of national base rates with a modification from the proposed rule that changes the baseline from 2015-2017 to 2016-2018 and a modification to exclude episodes from the baseline in which either the PC or TC is attributed to a provider with a Maryland, Vermont, or US Territory service location, rather than exclude episodes with RT services furnished in Maryland, Vermont, or a U.S. Territory as proposed. Its 32 national base rates for the RO Model performance period based on the criteria set forth for cancer type inclusion are summarized in Table 3 reproduced below (noting the removal of kidney cancer from the list of included cancer types discussed in section III.C.5.c).

TABLE 3 – National Base Rates by Cancer Type (in 2018 dollars)

RO Model-Specific Placeholder Codes[18]	Professional or Technical	Cancer Type	Base Rate
MXXXX	Professional	Anal Cancer	$3,001.19
MXXXX	Technical	Anal Cancer	$16,543.53
MXXXX	Professional	Bladder Cancer	$2,688.35
MXXXX	Technical	Bladder Cancer	$13,291.62
MXXXX	Professional	Bone Metastases	$1,398.14
MXXXX	Technical	Bone Metastases	$5,971.73
MXXXX	Professional	Brain Metastases	$1,601.70
MXXXX	Technical	Brain Metastases	$9,648.92
MXXXX	Professional	Breast Cancer	$2,081.47
MXXXX	Technical	Breast Cancer	$10,128.61
MXXXX	Professional	Cervical Cancer	$3,829.34
MXXXX	Technical	Cervical Cancer	$17,581.18
MXXXX	Professional	CNS Tumor	$2,510.55
MXXXX	Technical	CNS Tumor	$14,711.14
MXXXX	Professional	Colorectal Cancer	$2,449.38
MXXXX	Technical	Colorectal Cancer	$12,039.84
MXXXX	Professional	Head and Neck Cancer	$3,019.00
MXXXX	Technical	Head and Neck Cancer	$17,485.19
MXXXX	Professional	Liver Cancer	$2,082.23

[18] The final HCPCS codes specific to the RO Model would be published in an upcoming quarterly update of the CY 2020 Level 2 HCPCS code file.

TABLE 3 – National Base Rates by Cancer Type (in 2018 dollars)			
RO Model-Specific Placeholder Codes[18]	**Professional or Technical**	**Cancer Type**	**Base Rate**
MXXXX	Technical	Liver Cancer	$11,976.09
MXXXX	Professional	Lung Cancer	$2,181.23
MXXXX	Technical	Lung Cancer	$11,993.83
MXXXX	Professional	Lymphoma	$1,690.41
MXXXX	Technical	Lymphoma	$7,854.53
MXXXX	Professional	Pancreatic Cancer	$2,394.14
MXXXX	Technical	Pancreatic Cancer	$13,384.14
MXXXX	Professional	Prostate Cancer	$3,260.97
MXXXX	Technical	Prostate Cancer	$20,248.82
MXXXX	Professional	Upper GI Cancer	$2,585.57
MXXXX	Technical	Upper GI Cancer	$13,530.21
MXXXX	Professional	Uterine Cancer	$2,435.59
MXXXX	Technical	Uterine Cancer	$11,869.29

d. Application of Trend Factors to National Base Rates

CMS proposed to apply a trend factor to the different national base rates. 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 proposed that these calculated trend factors would 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 proposed 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 trended national base rates. The trended national base rates for 2020 would be made available on the RO Model's website once CMS issued the CY 2020 OPPS and PFS final rules that establish payment rates for the year. CMS noted that to the extent that it introduces new HCPCS codes that CMS determines should be included in the RO Model, it proposed 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.

Comments/Responses: While a few commenters expressed support for the proposal to update the trend factor using the most recent data available, others opposed the application of the trend factor for various reasons. Concerns included that the trend factor would not provide an adequate safeguard for innovation before new technology has a significant foothold in the marketplace. Others suggested modifications to the trend factor including carve-out payments for new service lines and recalculating the trend factor denominator based on a more recent year rather than 2017. Several commenters requested additional information on how the trend factor was calculated.

CMS in its reply notes that its trend factor will reflect updates to input prices as reflected in updated PFS and OPPS rates. It emphasizes that prospective payments, in general, are not designed to reflect specific investment decisions of individual providers and suppliers, such as practice-specific technology acquisition. CMS will update the year used in the trend factor to reflect the most recent data. For example, for PY 1, CMS will calculate the trend factor as:

2021 (PY1) Trend factor = (2018 volume * 2021 corresponding FFS rates as paid under OPPS or PFS) / (2018 volume * 2018 corresponding FFS rates as paid under OPPS or PFS)

Final Decision: CMS finalizes its proposals with a modification to the years used in the trend factor's numerator and denominator calculation. For the trend factor's numerator calculation, the most recent calendar year with complete data used to determine the average number of times each HCPCS code was furnished will be 2018 for PY1, 2019 for PY2, and so forth. The corresponding FFS payment rate (as paid under the OPPS and PFS) included in the numerator calculation is still that of the upcoming PY (2021 payment rates for PY1, 2022 payment rates for PY2, and so forth). The trend factor's denominator calculation will use data from 2018 to determine: (a) the average number of times each HCPCS code (relevant to the component and the cancer type for which the trend factor will be applying) was furnished; and (b) the corresponding FFS payment rate. The denominator does not change over the Model's performance period unless CMS proposes to rebaseline, which it would need to propose through future rulemaking.

e. Adjustment for Case Mix and Historical Experience

(1) Case Mix Adjustments

CMS proposed 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 proposed 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.[19]

As described in the proposed rule, CMS stated 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 stated that it would use Ordinary Least Squares (OLS) regression models, one for the PC and one for the TC, to identify the 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 clarified in the proposed rule 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 consider more recent changes in the case mix of their beneficiary population. For example, CMS stated that it would use data from 2015-2017 for PY1, data from 2016-2018 for PY2, data from 2017-2019 for PY3, etc.

Comments/Responses: Commenters were generally supportive of CMS' proposal to have case mix adjustments. Many offered suggestions, such as designing the case mix adjustments to be cancer specific rather than participant specific. Many suggested additional clinical factors that should be included in the model such as disease stage, line of treatment, comorbidities, treatment intent, and change in patient acuity over the course of the episode. Other commenters simply wanted clarity on the OLS model used to derive the case mix adjustments including why cancer type is included and the weight of each variable used to calculate the case mix adjustment.

CMS replies that there are not enough episodes to design a separate case mix adjustment approach for each cancer type, so it has chosen to create a single case mix adjustment approach across all cancer types. It also notes that it does not have clinical data available to further delineate severity of a patient's cancer, such as disease stage. It notes that it will be collecting clinical data from RO participants so that it can assess the potential utility of additional clinical

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

data for monitoring and evaluating episode payment amounts (see section III.C.8.e). CMS states that it includes cancer type in the case mix adjustment to capture the proportionate share of each cancer type in an RO participant's beneficiary population and assess the resulting effects of the particular mix of cancer types treated by that RO participant on cost. CMS provides additional explanation on its model but does not publish the details on the regression models, such as the coefficients or provide illustrative examples of these calculations, in the final rule.

Final Decision: CMS finalizes the case mix adjustment with modification. The formula that constitutes either the PC or the TC case mix adjustment for an RO participant, that is the difference between an RO participant's predicted payment and an RO participant's expected payment, divided by the expected payment, will not be modified. CMS modified the way in which it will calculate the expected payments. For calculating the expected payment for each RO participant, rather than using average Winsorized episode payments for each cancer type as proposed, CMS will use a second regression model that calculates expected payment amounts based on cancer type alone. By doing so, CMS states that this will align the use of regression models in the numerator and denominator of the case mix calculation.

(2) Historical Experience Adjustment and Blend (Efficiency Factor in Proposed Rule)

CMS also proposed a historical experience adjustment for an RO participant. To determine historical experience adjustments for a RO participant CMS proposed 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 would be given over the course of the RO Model's performance period.

CMS proposed 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.

Comments/Responses: Commenters were generally not supportive of the historical experience adjustments for various reasons. One commenter recommended that this adjustment be removed entirely as the national base rates are disproportionately determined by the Winsorized historical payment, and thus preventing the adoption of a truly site neutral policy for radiation oncology.

Others recommended removing this adjustment and instead adjust the national base rates through a blend of a participant's historical experience with the national historical experience and corresponding regional historical experience. For the efficiency factor, many commenters recommended that this factor be removed for efficient practices. MedPAC believed, for example, that this factor, as applied, would reward historically inefficient providers and suppliers, and penalize historically efficient provider and suppliers.

CMS in its response states that its analysis show that the variation across regions of the country is low, so it believes that a regional historical experience adjustment is not necessary. It does not want to remove the historical experience adjustments as this would cause an abrupt transition in payment determined largely or entirely by national base rate amounts. Using 2016-2018-episode data, CMS calculates (as shown in Table 4 in the final rule, reproduced below) what proportion of CCNs and TINS are historically efficient or inefficient.

Table 4. Percent of RO Participants That Are Historically Efficient, Inefficient, or Neither.

	Professional	**Technical**
Efficient (historical experience adjustment < 0.0)	25.6%	36.2%
Inefficient (historical experience adjustment > 0.0)	49.9%	27.6%
Neither (historical experience adjustment = 0.0)*	24.5%	36.2%

For the efficiency factor, CMS believes that renaming the efficiency factor as the "blend" will help clarify what it represents and call attention to its purpose of setting the precise level of impact that the RO participant's specific historical experience has on the episode payment amounts. It provides some examples to illustrate how this "blend" would work in practice. If RO participants spent less historically (on average) than the average spend of all HOPDs nationally, then their payment amount is 90 percent of what they would have been paid historically for the PC and/or TC of the respective cancer type furnished and 10 percent of the corresponding national base rate. This will result in the historically efficient RO participant seeing an increase in payment compared to historical amounts prior to other adjustments. CMS states that if it removes the efficiency factor for efficient providers and suppliers, this will prevent the Model from maintaining costs or achieving savings. Similarly, if RO participants spent more historically (on average) than the average spend of all HOPDs nationally, then their payment amount begins at 95 percent of what would have been paid historically for the PC and/or TC of the respective cancer type furnished and 5 percent of the corresponding national base rate. This will result in the historically inefficient RO participant seeing a decrease in payment compared to historical amounts. This difference would be gradual over time to allow the RO participant to gradually adjust to the new model payments.

Final Decision: CMS finalizes the historical experience adjustment as proposed, and will finalize the efficiency factor, henceforth called the "blend," with modification, codified at §512.255(d). For RO participants with a PC or TC historical experience adjustment with a value greater than zero (that is, historically inefficient), the blend will be 90/10 in PY1 where 90 percent of payment is determined by the historical experience of the RO participant and 10 percent of

payment is determined by the national base rates. The blend will be finalized as proposed to be 90/10 in PY1, 85 /15 in PY2, 80/20 in PY3, 75/25 in PY4 and 70/30 in PY5. For those RO participants with a PC or TC historical experience adjustment with a value equal to or less than zero (that is, historically efficient), the blend will be finalized as proposed to be fixed at 90/10 over the Model's performance period (PY1-PY5).

(3) Application of the Adjustments

To apply the case mix adjustment, the historical experience adjustment, and the efficiency factor (now referred to as the blend factor) to the trended national base rates CMS stated in the proposed rule 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 32 RO participant-specific episode payments for Dual participants and a total of 16 RO participant-specific episode payments for Professional participants and Technical participants.

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

Final Decision: CMS received no comments on this proposal and is finalizing this provision with only the modification that reflects the removal of kidney cancer. CMS finalizes this provision with modification in that calculations for the corresponding case mix adjustment, historical experience adjustment, and blend for the PC and TC, yielding a total of 32 (not 34) RO participant-specific episode payments for Dual participants and a total of 16 (not 17) RO participant-specific episode payments for Professional participants and Technical participants

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

CMS proposed 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.

Comments/Responses: Several commenters recommended that CMS exclude providers and suppliers with fewer than 60 episodes during the 2015-2017 period, rather than just adjusting their episode payments. Some proposed that a stop-loss policy be added to protect those participants at risk for significant loss.

In its reply, CMS notes its low-volume opt-out option (see Section III.C.3.c of this summary) will address many of these concerns and applies to those provider and suppliers that furnish fewer than 20 episodes. It also agrees with commenters that RO participant with fewer than 60 episodes during the 2016-2018 period will not have an historical experience adjustment nor a case mix adjustment for PY 1. It also agrees with commenters regarding the need for a stop-loss policy and modifies its proposal to include a stop-loss limit of 20 percent for the RO participants that have fewer than 60 episodes during the baseline period.

Final Decision: CMS finalizes its policy at §512.255(c)(7) with the modification that if an RO participant continues to have fewer than 60 episodes attributed to it during the 2017-2019 period, then the RO participant will not have a case mix adjustment for PY2. However, if the RO participant has 60 or more attributed episodes during the 2017-2019 period, then the RO participant will have a case mix adjustment for PY2 and the remaining PYs of the Model. In PY3-PY5, CMS states it will reevaluate those same RO participants that did not receive a case mix adjustment the previous PY to determine the number of episodes in the rolling three-year period used in the case mix adjustment for that performance year (for example, PY3 will be 2018- 2020).

It is also finalizing a stop-loss policy at §512.255(b)(7) for RO participants with fewer than 60 episodes. Using no-pay claims to determine what these RO participants would have been paid under FFS as compared to the payments they received under the Model, CMS will pay these RO participants retrospectively for losses in excess of 20 percent of what they would have been paid under FFS. Payments under the stop-loss policy are determined at the time of reconciliation.

(5) 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 proposed 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 meet 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 stated in the proposed rule that it proposed this policy 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 proposed that the RO Model requires advanced notification. 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.

Final Decision: CMS received no comments on its proposal. It finalizing its proposal at §512.255(b)(5), with modification to align with the finalized RO Model performance period so that this provision would apply to a new TIN or CCN that results from a merger, acquisition, or other new clinical or business relationship that occurs prior to October 3, 2025 (changed from October 3, 2024).

f. Apply a Discount Factor

After applying participant-specific adjustments to the trended national base rates, CMS proposed to next deduct a percentage discount from those amounts for each performance year. The discount factor would not vary by cancer type. The proposed discount factor for the PC would be 4 percent and the proposed discount factor for the TC would be 5 percent. CMS believed these figures would 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 proposed to apply these discount factors to the RO participant-adjusted and trended payment amounts for each of the RO Model's performance years.

Comments/Responses: Most commenters suggested reducing the discount factor for both the PC and TC down within the 1 and 3 percent range or phasing in the percentage of the discount factor over several PYs. They cited other models, such as the CJR Model and BPCI Advanced Model, all of which had lower discount factors than what CMS proposed. Several commenters also asked for a rationale as to why the discount factor for the TC is higher than that of the PC.

CMS notes its appreciation for the comments and suggestions. It believes that reducing the discount factors to 3.75 percent and 4.75 percent for the PC and TC, respectively, balances the need for the model to achieve savings while also reducing the impact on RO participants. It also explains that it believes the PC should have a lower discount factor than the TC given the 2 percent quality withhold applies to the PC whereas the TC will have a 1 percent patient experience withhold beginning in PY 3.

Final Decision: CMS finalizes this provision with modification in that the discount factors for the PC and TC will each be reduced by 0.25 percent. The discount factor for the PC will be 3.75 percent and the discount factor for the TC will be 4.75 percent. Additionally, CMS modifies the regulatory text at §512.205 to specify the Discount factor means the set percentage by which CMS reduces payment of the PC and TC. The reduction on payment occurs after the trend factor, the geographic adjustment, and the RO Model-specific adjustments have been applied but before beneficiary cost-sharing and standard CMS adjustments, including sequestration, have been applied.

g. Applying Withholds

CMS proposed 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) Incorrect Payment Withhold

CMS proposed 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 proposed a withhold for these circumstances 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. As noted in the proposed rule, CMS analysis of claims data showed 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.

CMS proposed 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) Quality Withhold

CMS also proposed 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 proposed 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) Patient Experience Withhold

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

Comments/Responses: Most commenters expressed concerns about the potential financial burden the incorrect payment withhold, the quality withhold, and the patient experience withhold could pose for RO participants. A few argued that the withholds are punitive in nature as they occur prior to the delivery of services. One commenter suggested that CMS recoup funds from RO participants rather than withhold funds.

In its response, CMS states that it expects incomplete episodes and duplicate payments to be uncommon and that the burden of recoupment (instead of a withhold) would be too burdensome for CMS. Recognizing stakeholder concerns' regarding the cash flow burden and given that funds withheld are not subject to coinsurance collection from beneficiaries or their supplemental insurance, CMS reduces the incorrect payment withhold to 1 percent rather than 2 percent. CMS states that it intends to reevaluate this amount and need for the incorrect payment withhold in PY3. It believes that the upfront quality withhold will provide the incentive for RO participants to provide high-quality care.

Final Decision: CMS finalizes its proposals on incorrect payment withhold, quality withhold, and patient experience withhold, with modifications. It finalizes the quality withhold amounts as proposed beginning in PY1 (January 1, 2021, through December 31, 2021) and the patient experience withhold as proposed beginning in PY3 (January 1, 2023 through December 31, 2023), but reduces the incorrect payment withhold to 1 percent beginning in PY1. CMS has modified the text of the regulation at §512.255(h), (i), and (j) to describe how incorrect payment withhold, quality withhold, and patient experience withhold would be applied to the national base rates, in a manner consistent with the regulatory text for how other adjustments (for example, the discount factor and geographic adjustment) are applied to the national base rate.

h. Adjustment for Geography

CMS proposed 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.

Comments/Responses: Several commenters stated that all components of the pricing methodology should be based on geographically standardized payments as it would be inappropriate for CMS to compare geographically adjusted historical payments with non-geographically-adjusted predicted payments.

CMS clarifies in its response that episode payments are standardized based on using service volume and national fee schedule prices. In addition, CMS notes that this method of geographic adjustment is the standard way it pays through PFS and OPPS and wants to design an approach that could be implemented on a broader scale, if the model is successful.

Final Decision: CMS finalizes its proposal on the geographic adjustment with modification to clarify that although the RO Model-specific RVU values are derived from the national base rates it will use only 2018 episodes to calculate the implied RVU shares, or the proportional weights of each of the three components (Work, PE, and MP). These RVU shares are part of the calculus for determining the RO Model-specific RVU values.

Table 7 in the final rule provides the relative weight of the RO Model-specific RVUs shares for the PC and TC that will be used to apply the PFS GPCIs.

Table 7 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. Applying Coinsurance

CMS proposed 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.

In the proposed rule, CMS also states it 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.

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.[20]

Comments/Responses: Comments on applying coinsurance were primarily related to role of secondary payers, MediGap, and Medicaid and the impact of the RO Model on beneficiaries. Clarification was sought on whether secondary payers would be held accountable if the RO episode is not allowed and payment is recouped. Several commenters expressed concern that the RO Model's policy of imposing a 20 percent coinsurance payment on the episode payment amount would be confusing to beneficiaries. These commenters also requested specific guidance on creating a payment plan for beneficiaries and expressed concern that RO participants will not have the billing staff to implement such a plan. Others expressed a concern that beneficiaries who receive fewer services or lower-cost RT services than average for their cancer type would pay more in cost-sharing in a participating region than if they had received the same treatment in a non-participating region.

CMS acknowledges commenters' concerns about secondary payers and states that it expects to provide RO participants with additional instructions for billing, particularly as it pertains to secondary payers and collecting beneficiary coinsurance. Additional instructions will be made available through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website. With respect to beneficiaries being confused, CMS does not believe that this would be the case given that 20 percent is the standard coinsurance policy under Medicare. CMS also notes that while it encourages RO participants to implement payment plans for RO beneficiaries, neither the proposed rule nor the final rule requires RO participants to implement payment plans. It stresses, however, that should an RO participant offer a payment plan it may not be used as a marketing tool to influence beneficiary choice or health care provider. It also believes that, on average, the total coinsurance paid by RO beneficiaries would be lower than what they would have paid under Medicare FFS for all the services included in the RO episode as it is reduced by both the discount factor and the withholds.

Final Decision: CMS finalizes, in part, its proposal related to coinsurance. Specifically, CMS codifies at 512.255(b)(12) the requirement that RO participants offering a payment plan may not use the availability of the payment plan as a marketing tool and may inform the beneficiary of the availability of the payment plan prior to or during the initial treatment planning session and as necessary thereafter. With respect to a subset of incomplete episodes, CMS is not finalizing its proposal that beneficiaries pay 20 percent of the episode payment. Accordingly, the beneficiary will owe 20 percent of the FFS amount for RT services furnished during an incomplete episode in which (1) the TC is not initiated within 28 days following the PC, (2) the RO beneficiary ceases to have traditional FFS Medicare prior to the date upon which a TC is initiated, even if that date is within 28 days following the PC, or (3) the RO beneficiary

[20] 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.

switches RT provider or RT supplier before all RT services in the RO episode have been furnished.

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

Tables 8 and 9 in the final rule illustrate possible participant-specific professional and technical episode payments paid by CMS to one entity (Dual participant) or two entities (Professional participant and Technical participant) for the furnishing of RT professional services and RT technical services to an RO beneficiary for an RO episode of lung cancer. These tables are updated versions of Tables 5 and 6 from the proposed rule that reflect the finalized policies.

Tables 8 and 9 also reflect the following technical changes to properly reflect the way in which the claims systems process payment: (1) the change in sequence related to the geographic adjustment; (2) a change in the way the withhold calculation is displayed; (3) a change in the way discount factor and withholds are displayed; and (4) a change in the way the total episode payment amount is split between the start of episode (SOE) payment and end of episode (EOE) payment. Table 8 is reproduced below for illustration. Table 9 in the final rule details an illustrative example for a participant-specific technical episode payment.

Table 8: 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
SPLIT for SOE/EOE payments (d)	$1,120.60	d =c/2
Geographic Adjustment (e)	1.02	
Subtotal1 (f)	$1,143.01	f = d * e
Case Mix Adjustment (g)	0.02	For example (102-100) / 100
Historical Experience Adjuster (h)	0.14	For example (116-102) / 100
PY1 Blend (i)	0.90	
Adjustments combined (j)	1.15	j = g + (h * i) + 1
Subtotal (k)	$1,309.89	k = j * f
Discount Factor (l)	0.0375	
Subtotal (m)	$1,260.77	m = (1-l) * k
Withhold #1 (Incorrect Payment) (n)	0.01	
Withhold #2 (Quality Performance) (o)	0.02	
Total Withhold (p)	0.03	p = n + o
Half of Total Episode Payment to RO Participant without sequestration (q)	$1,222.95	q = (1-p) * m

Beneficiary Coinsurance for SOE payment Determined (r)	$244.59	r = q * 0.20
SOE Participant Payment	$978.36	s = q * 0.80
Sequestration Claims Payment Adjustment to Participant Payment (t) [t = half of the total participant-specific professional episode payment]	$958.79	t = s * 0.98
Episode Payment 1: SOE (u)*	**$958.79**	**u = t**
Episode Payment 2: EOE (v)*	**$958.79**	**v = t**
Total Episode Payment to RO Participant (w)	**$2,406.76**	**w = u+v+2r**

^ All numbers are rounded to two decimal places.

Table 10 in the final rule (reproduced below) summarizes the data sources and time periods used to determine the values of key pricing components resulting from these modifications.

TABLE 10: DATA SOURCES AND TIME PERIODS USED TO DETERMINE VALUES OF THE RO MODEL'S KEY PRICING COMPONENTS

Key Components	Data Source	PY 1 (2021)	PY 2 (2022)	PY 3 (2023)	PY 4 (2024)	PY 5 (2025)
National Base Rates	HOPD episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Trend factor	Non-participant episodes	(2018 volume * 2021 rates) / (2018 volume * 2018 rates)	(2019 volume * 2022 rates) / (2018 volume * 2018 rates)	(2020 volume * 2023 rates) / (2018 volume * 2018 rates)	(2021 volume * 2024 rates) / (2018 volume * 2018 rates)	(2022volume * 2025 rates) / (2018 volume * 2018 rates)
Winsorization thresholds	HOPD episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Case mix coefficients	HOPD episodes	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Case mix values [and whether eligible (>60 episodes) to receive case mix adjustment]	Participant specific	2016-2018	2017-2019	2018-2020	2019-2021	2020-2022
Historical Experience adjustment [and whether eligible (>60 episodes) to receive historical experience adjustment]	Participant specific	2016-2018	2016-2018	2016-2018	2016-2018	2016-2018
Blend for RO participant with historical experience adjustment greater than 0.0	N/A	0.90	0.85	0.80	0.75	0.70

Blend for RO participant with historical experience adjustment equal to or less than 0.0	N/A	0.90	0.90	0.90	0.90	0.90
RVU shares used in the PFS geographic adjustment	HOPD episodes	WORK/PE/ MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/ MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/ MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/ MP shares PC (66/30/4) TC (0/99/1) 2018	WORK/PE/ MP shares PC (66/30/4) TC (0/99/1) 2018

7. Professional and Technical Billing and Payment

CMS proposed 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.

In the proposed rule, CMS stated that to reduce burden on RO participants, it proposed 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.

As stated in the proposed rule, 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 an RO Model-specific HCPCS code 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 a 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 as services are furnished and would otherwise be billed under the Medicare FFS systems. CMS stated 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,	Claim would be paid using the rate assigned to that RO Model-specific HCPCS code without the adjustments.

but the CCN or TIN is not yet identified as a RO participant in the claims systems	

CMS stated 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.

Comments/Responses: Most commenters expressed concerns about the billing requirements for the proposed RO Model. This included that current billing systems are designed to bill after the services are furnished and not before. An additional complexity is that many health care providers and health systems do not do their own internal billing and will need additional time to work out billing details with their external third-party vendors. Many commenters were also concerned about the lack of details regarding billing requirements for the proposed RO Model including how to handle prospective HCPCS codes and the no-pay claims. Others expressed concern about the proposed billing timing requirements stating that it was not clear from the proposed rule how Technical participants would know when a Professional participant started an episode for one of their patients at the time that patient presented for radiation therapy treatment.

Multiple commenters expressed concerns about the timing of its proposed payments and that most provider and suppliers, based on CMS data, would have to wait more than a month to be able to bill for care that has already been provided. They stated that billing delays would impact their cash flow, create hardships in their ability to pay bills, to order medical supplies and to provide the necessary staffing coverage. As a potential solution, most commenters requested that providers and suppliers be able to receive the 2nd payment sooner than 90 days, ideally when the services were complete. Commenters also asked if allowable rates will be available for the new codes 30 days prior to the program start.

Commenters also expressed confusion about how to treat certain circumstances. For example, some commenters stated that CMS does not describe how a Professional participant (that is, the individual radiation oncologist or the radiation oncology physician group/practice TIN) that furnishes their RT services at an exempt facility (ASC, PCH, CAH) is to bill for those encounters. Another commenter asked how it should bill for a patient that presents with two separate diagnoses that are included within the model, such as a lung cancer patient with brain metastasis.

In response to concerns about billing requirements, CMS believes that it has created a billing process that will be easily implemented within current systems. It states additional guidance will be forthcoming by CMS through the Medicare Learning Network (MLN Matters) publications, model-specific webinars, and the RO Model website. CMS believes that Technical participants should know when an episode begins as RT delivery services cannot be administered to a patient without a signed radiation prescription and the final treatment plan. Nonetheless, the submission and payment of TC claims is not dependent on the submission of PC claims. If the TC claims with the SOE modifier is received first, the claims system will estimate the first day of the episode. A similar process will occur for EOE claims.

CMS agrees, in part, with commenters about the timing of its proposed payments. CMS modifies its policies to permit an RO participant to submit the EOE claim after the RT course of treatment has ended, but no earlier than 28 days after the initial treatment planning service was furnished. It stresses that 28 days after the initial treatment planning service was furnished is the earliest that EOE claims should be submitted, because if the TC has not been furnished to an RO beneficiary after 28 days, this would be an incomplete episode, as defined at §512.205. It also indicates that the RO Model-specific HCPCS codes will be posted on the RO Model website at least 30 days prior to the start of the model.

For a Professional participant that provides its services at an exempt facility, such as an ASC, CMS states that it has worked closely with the Provider Billing Group within CMS, the MACs, and the Shared System Maintainers to establish the least burdensome way to submit claims that do not follow the standard course of an episode. CMS determined that the use of an established modifier for professional claims and a condition code for HOPD claims would be the best way to indicate that certain services fall outside of an RO episode and should be paid FFS. When services are furnished by a participant and a non-participant, these scenarios would be considered incomplete episodes. In situations where a patient presents with separate diagnoses that are included in the model, CMS states that only one RO Model-specific HCPCS code will apply to an RO episode even if the RO beneficiary has more than one included cancer type for which they are receiving services. The RO participant would choose which one to bill, unless, for example, the RO beneficiary is receiving RT services for just one, in which case this cancer type would be billed.

Final Decision: CMS finalizes its proposals related to billing and payment at §512.260 and §512.265, with modifications. Specifically, it adds a new paragraph (d) to §512.260 to codify the requirement that an RO participant submit no-pay claims for any medically necessary RT services furnished to an RO beneficiary during an RO episode pursuant to existing FFS billing processes in the OPPS and PFS, as described in this section of the final rule. Additionally, as noted earlier, CMS is permitting an RO participant to submit the EOE claim after the RT course of treatment has ended, but no earlier than 28 days after the initial treatment planning service was furnished. Regardless of when the EOE claim is submitted, the episode duration remains 90 days. Any RT services furnished after the EOE claim is submitted will not be paid separately during the remainder of the RO episode.

Further, CMS clarifies at §512.245(b) that if an RO beneficiary dies after both the PC and the TC of the RO episode have been initiated, the RO participant(s) would be instructed to bill EOE claims and would be paid the second half of the episode payment amounts regardless of whether treatment was completed. It also clarifies that each RO participant will receive both installments of the episode payment regardless of whether the RO beneficiary dies or elects the Medicare hospice benefit before the relevant course of RT treatment has ended.

8. Quality

CMS finalizes its proposal 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 Payment System (MIPS).

CMS believes all the 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 11 (reproduced below) summarizes the finalized quality measures, level of reporting, and the measure' status as pay-for-reporting or pay-for-performance. CMS finalizes its proposal to require 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. Instead of submitting quality data beginning in March 2021, CMS finalizes the first annual quality data submission will occur in March 2022. CMS finalizes the collection of clinical data elements will begin January 1, 2021 with the first submission due in July 2021. CMS plans to provide the final list of clinical data elements on the RO Model website prior to the start of PY1.

CMS considers the RO Model as an Advanced APM and an MIPS APM for the Quality Payment Program (QPP).

Table 11: 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 #0383; 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 #0326; 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. Measure Selection

CMS discusses the reasons it *finalized the four quality measures* for the RO Model. CMS believes these measures 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, these measures allow 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 determined there are not any available or applicable outcome measures for the RO Model the requirement for an Advanced APM to include at least one outcome measure does not apply for the first performance period. If a relevant outcome measure becomes available, CMS will 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.

A few commenters supported the use of NQF-endorsed measures; other commenters specifically opposed using non-NQF endorsed measures; and other commenters recommended other measures, including allowing national accreditation through the American College of Radiology (ACRO) or American Society for Radiation Oncology (ASTRO) to be sufficient for meeting quality standards. CMS responds that NQF endorsement is only one of several important criteria it considered for selecting quality measures and that NQF endorsement is not a requirement for the RO Model. CMS believes that the "Treatment Summary Communication" measure captures relevant information about a patient's continuity and coordination of care. In response to commenters recommending CMS only include safety measures, CMS states it will assess patient safety via claims, site visits, and other data that is required to be reported for monitoring and evaluation. CMS agrees with commenters that accreditation by national recognized organizations may be an indicator of the overall quality of care provided but it does not believe that accreditation is sufficient to determine the quality of care delivered in radiation oncology. CMS notes that it may consider using an optional web-based survey to gather data about other important information, including participants accreditation status. CMS disagrees with a recommendation that quality measures should reflect variation in accreditation status and the equipment used for treatment. CMS believes that quality measures should focus on the patient and the episode of care and not be based solely on the type of equipment used or accreditation status. CMS also does not agree with the recommendation for a voluntary phase-in period to collect quality measure data because it believes there is sufficient time for RO participants to develop and implement necessary changes to facilitate data collection.

CMS acknowledges the suggestions for additional quality measures and will consider revisions to the finalized measure set for future model years. CMS agrees with commenters, including MedPAC, that outcome measures are important to include in the model's measure set. CMS considered several outcome measures but did not include these because of concerns over attributing outcomes, such as hospital admissions or ED visits, directly to RT measures. CMS also considered using the Oncology Care Model (OCM) outcome measures for the RO Model, but decided it would be difficult to determine if the outcomes occurred due to complications from the RT service, chemotherapy, or other reasons. CMS appreciates commenters' suggestions for using a qualified clinical data registry (QCDR) to track outcomes and will monitor this suggestion for consideration in future rulemaking.

b. RO Model Measures and CAHPS® Cancer Care Survey for Radiation Therapy

CMS describes each measure and its reasons for its selection.

Oncology: Medical and Radiation – Plan of Care for Pain (NQF #0383; 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.[21]
- 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 OCM, and MIPS.
    - The RO Model will adopt the measure according to the most recent version of the specifications, which is under review at the NQF this Fall.
- The measure is a pay-for-performance measure.

In response to comments about the status of the NQF review, CMS notes that it intends to use the most recent specifications approved by NQF unless those specifications are inconsistent with the specifications used in MIPS and it would use the MIPS specifications. Thus, for each PY, CMS will utilize the specifications of the measure that align with the most recent MIPS year specifications. CMS notes that if it does not align the measure with the MIPS specifications, it will not be able to compare MIPS and RO participants.

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.[22]
- 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 is a pay-for-performance measure.

A few commenters supported including this measure; a few commenters recommended not adopting this measure because it is topped out, is outside the direct control of radiation oncologists, and imposes a burden because it is not easily captured in the medical record. Commenters suggested that CMS work with specialty societies and other stakeholders to develop appropriate measures for radiation therapy. CMS disagrees with commenters and notes that in the MIPS program, the measure is not topped-out and even if the measure were to become topped-out it believes there is value in continuing a topped-out measure to prevent a decrease in performance on an important aspect of care. CMS acknowledges that screening for depression and follow-up care is not traditionally within the purview of radiation oncologists, but it believes the RO Model presents an opportunity to focus on a comprehensive understanding of a patient's health when receiving RT services. Because this is an existing MIPS measure, CMS expects that data is being captured or could be captured in the medical record. CMS will use the MIPS benchmark and does not agree with a commenters recommendation to establish a benchmark specific to radiation oncology patients.

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

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.[23]
- 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 is a pay-for-performance measure.

A few commenters supported including this measure; a few commenters recommended not adopting this measure because it is topped out, is outside the direct control of radiation oncologists, imposes a burden because it is not easily captured in the medical record, and does not account for patients' receipt of survivorship care plans. CMS again disagrees with commenters and notes that in the MIPS program, the measure is not topped-out and even if the measure were to become topped-out it believes there is value in continuing a topped-out measure to prevent a decrease in performance on an important aspect of care. CMS acknowledges that advanced care planning is not traditionally within the purview of radiation oncologists, but it provides an important opportunity for discussion of care planning. Because this is an existing MIPS measure, CMS expects that data is being captured or could be captured in the medical record. CMS will use the MIPS benchmark and does not agree with a commenters recommendation to establish a benchmark specific to radiation oncology patients. CMS notes that an advanced care plan is different from the Survivorship Care Plans which include information about a patient's treatment, the need for future check-ups and cancer tests, and potential long-term late effects of treatment. CMS clarifies that the numerator of the Advance Care Plan measure captures how many patients were asked if they have an advance care plan and is agnostic as to whether or not they have a plan.

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 physician(s) providing continuing care and to the patient within one month of completing treatment.[24]
- 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 is a pay-for-reporting measure.

[23] Detailed measure specifications are at https://qpp.cms.gov/docs/QPP_quality_measure_specifications/Claims-Registry-Measures/2018_Measure_047_Registry.pdf.
[24] Detailed measure specifications can be found at http://www.qualityforum.org/QPS/0381.

- CMS will establish a benchmark for this measure and it will become a pay-for-performance in PY3.

A few commenters supported this measure with some supporting implementation of this measure as pay-for-performance in PYs 1-2. CMS responds that the measure is finalized as pay-for-reporting in PY1 and PY2 in order to establish historical data to set a benchmark for use during the pay-for-performance years. CMS plans to provide information regarding the benchmark on the RO Model website. CMS acknowledges commenters' concerns about the measure, including lack of NQF endorsement, but it believes this is an important measure to ensure that the radiation oncology treatment documentation is appropriately transitioned to the physician responsible for the patient's ongoing care.

CAHPS Cancer Care Survey for Radiation Therapy[25]

- CMS finalizes its proposal to have a CMS-approved contractor administer the survey. Instead of administering the survey beginning April 2020, CMS finalizes that the survey will be administered beginning in April 2021.
- CMS states that variations of the CAHPS survey are widely used to measure 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 through rulemaking. The measure would be considered a pay-for-performance measure beginning in PY3.

In response to recommendations to implement the survey before PY3, CMS notes that it will begin fielding the survey in PY1 and it needs time to derive and test which survey domains should be included in the Aggregate Quality Score (AQS). It anticipates it will include patient experience measures in the calculation of the AQS, after future rulemaking, in PY3. CMS acknowledges that there are significant challenges to implementing patient experience measures but these should not preclude working to collect and analyze the data to achieve the goal of improving patient care. CMS notes that AHRQ has tested the survey for reliability and validity to address issues of comparability across practices and patient characteristics. CMS appreciates comments related to the survey methodology and it will consider these comments in future rulemaking.

c. Form, Manner, and Timing for Quality Measure Data Reporting

CMS *finalizes its proposals for the data collection processes* for the quality measures:

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

[25] The CAHPS Cancer Care survey can be found at https://www.ahrq.gov/cahps/surveys-guidance/cancer/index.html.

(ii) Require the data be reported for all applicable patients on the measure specifications. Data will 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 will 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 cases, the participant will 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 will 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 will not adjust the reporting period to reflect the model time period.
- A schedule for data submission will be posted on the RO Model website: https://innovation.cms.gov/initiatives/radiation-oncology-model/.

CMS also *finalizes its proposal that measures may undergo non-substantive technical updates* to remain current. This may result from the NQF annual and/or triennial maintenance processes for endorsed measures and through CMS review.

In response to commenters recommendation that CMS pay RO participants to establish quality data reporting because of the associated costs, CMS notes that it will be paying for the administration of the CAHPS Cancer Care Survey but it does not believe additional payments or additional management fees are necessary. CMS clarifies the Monthly Enhanced Oncology Services payment in the OCM is for the provision of Enhanced Services and is not payment for collecting quality data.

In response to comments about the aggregation of the quality measure data, CMS states that RO participants will be required to report aggregated numerator and denominator data, not individual patient-level data, for all patients as defined in the measure specifications. CMS believes it is important that the Model collects measures in the manner specified to ensure reliability of the

measure and also to comport with how the measure is specified and implemented in MIPS and other quality initiatives. It also believes that including all patients provides valuable information when assessing quality. CMS plans to provide the final list of clinical data elements on the RO Model website prior to the start of PY1.

In response to comments expressing concerns about the need to use a separate portal for submitting data, CMS states that a new, separate portal is necessary because the RO Model reaches across three different care settings. Data will be submitted through the RO Model secure data portal and technical support and education will be provided. CMS notes it will also post whether it will permit third-party data submission. In addition, CMS states the RO Model secure data portal will also allow RO participants access to claims data.

A few commenters recommended that the quality measures should be scored as electronic Clinical Quality Measures (eCQMs) and allow the use of certified EHR instead of utilizing a registry for submission of data. CMS explains that it is using the registry specification for the measures because they are the most widely used method of data submission and will allow more participants to submit data with the least impact on workflow. It also believes the data from registry measures are both highly reliable and valid. CMS plans to provide structured data reporting standards so that existing EHRs can be adjusted, if necessary, for RO participants. In response to concerns that there is not adequate time for EHR vendors to make necessary changes to the EHR, CMS believes the July 1, 2021 data for the submission of clinical data elements provides sufficient time for EHR vendors to develop appropriate changes. CMS will also provide the reporting standards to EHR vendors and the radiation oncology specialty societies prior to their inclusion in the Model.

d. Clinical Data Collection

CMS *finalizes its proposal that on a pay-for-reporting basis*, it will require Professional and Dual participants to report basic, clinical information that includes 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 clarifies this is an exhaustive list. CMS will determine the specific data elements and reporting standards prior to the start of the RO Model and will post this information on the RO Model website. CMS will provide education, outreach, and technical assistance.

CMS notes this information is not available in claims or captured in the quality measures. 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

are 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 *finalizes 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 is in addition to the four quality measures. CMS clarifies that the first submission for PY1 will be in July of PY1 and the second submission for clinical data for PY1 will be in January of PY2. The submission schedule for the following PYs will be similar and the final submission for PY5 will occur in January 2026.

CMS acknowledges the wide range of suggestions it received in response to its request for comments about clinical data elements reporting. It will review each suggestion as it considers which clinical data elements to include in the RO Model.

A few commenters opposed all clinical data reporting requirements because of the increased burden associated with these requirements. Several commenters recommended delaying or phasing-in the implementation of this requirement to allow vendors and RO participants sufficient time to update reporting specifications. Several commenters urged CMS to consider the HL7® FHIR®-based mCODE™ (Minimal Common Oncology Data Elements) as the core set of structured data elements for oncology EHRs. In response, CMS states that in order to reduce burden, it is aligning with other federal program requirements to the greatest extent practicable. CMS believes that the publication of this final rule provides RO participants with sufficient time to prepare before the start of PY1 on January 1, 2021. CMS notes it is aware of mCODE, but it is not confident it will be immediately accessible to all RO participants and it may not be feasible to test and implement mCODE before the beginning of the PY1. CMS will continue to monitor developments in EHR and interoperability. CMS agrees with comments encouraging CMS partner with the Office of the National Coordinator for Health Information Technology (ONC) and other federal agencies to facilitate interoperability that will provide secure and timely exchange of health information. CMS will also assess opportunities to coordinate on a minimum set of oncology data elements.

e. Connect Performance on Quality Measures to Payment

<u>Calculation for the Aggregate Quality Score (AQS)</u>
CMS *finalizes its proposal* that the AQS is based on each Professional and Dual participant's:

1. performance on the set of finalized quality measures compared to those measures' quality performance benchmarks;
2. reporting of data for the finalized pay-for-reporting measures; and
3. reporting of clinical data elements on applicable RO beneficiaries.

CMS *finalizes its proposal 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 finalized weighting for the AQS is:

Aggregate Quality Score = Quality Measure + Clinical Data

- 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 will 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 finalizes its proposal 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.[26] The MIPS program awards up to ten points, including partial points, for each measure and CMS finalizes its proposal 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 finalizes its proposal to use other appropriate national benchmarks. CMS will calculate a RO Model-specific benchmark from the previous year's historical performance data and if the historical performance data is not available, it will 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 will receive ten points for the measure. Participants that do not submit the measure as specified will receive zero points. For PY1, CMS finalizes that the Treatment Summary Communication measure is the only pay-for-reporting measure.

The total points awarded for each measure will also depend on the measure's weight. CMS finalizes its proposal 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 will award up to 10 points for each measure and then recalibrate the participant's measure scores to a denominator of 50 points.[27] When a participant does not have sufficient cases for a given measure, the measure will be excluded from the AQS denominator calculation and the denominator will be recalibrated to reach a denominator of 50 points.

As discussed in the final 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 receives 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 fails to report a measure, it will receive 0 out of 10 points for the measure and the participant will have a total of 40 possible points for the quality measure component. If a

[26] MIPS benchmarks are published annually at https://qpp.cms.gov/about/resource-library.
[27] The CAHPS Cancer Care Survey for Radiation Therapy will 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.

participant scores 20 points out of 40 possible points, the quality measure component score will be 25 points after recalibrating the denominator to 50 points ((20/40) * 50 = 25).

For the submission of reporting clinical data, *CMS finalizes its proposal* that Professional and Dual participants will either be considered "successful" reporters and receive full credit for meeting the requirements, or "not successful" reporters and not receive any credit. CMS defines 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 will receive 0 out of 40 points for the clinical data element component.

To calculate the AQS, CMS finalizes its proposal 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 is divided by 100 points to express the AQS as a percentage.

CMS provides two examples for calculation of the AQS. Table 12, 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 13, in the final rule, 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 12: 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 *In this example, the measure did not meet the minimum case requirements.*	0	0	
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 *finalizes its proposal to* continue to weight measures equally in PY 1 through PY5. Any updates would be proposed and finalized through rulemaking.

Several commenters opposed the 95 percent threshold for successful clinical data element reporting; a commenter urged CMS to adopt a three- to six-month reporting window for clinical data elements. CMS believes the 95 percent threshold is necessary to ensure that the data collected provides an accurate reflection of the RO participant's patient population. It believes that staggering the requirement would increase the operational complexity of the RO Model and increase participant's burden. CMS disagrees with recommendations that the four quality measures should be pay-for-reporting for at least the Model's first year. CMS reiterates its belief that participants have sufficient time during PY1 and before the first submission in March 2021 to understand these measures. CMS states it will provide education, outreach, and feedback reports to help participants understand the measures and submission systems.

In response to concerns about the Model's relative scoring methodology, CMS states it prefers a relative scoring system based on real world performance goals instead of absolute performance goals. CMS notes that although MIPS benchmarks are adopted in advance, they are based on historical performance and allow assessment based on real-world performance. CMS states it will consider these concerns, as it adopts benchmarks for the Treatment Summary Communication and CAHPS Cancer Care survey measures in future rulemaking.

Applying the AQS to the Quality Withhold

CMS *finalizes its proposal* to multiply the Professional of Dual participant's AQS (as a percentage) against the 2 percent quality withhold amount. For example, if a participant receives an AQS of 88.3 out of a possible 100, the participant will receive a 1.77 percent quality reconciliation payment amount (0.883 * 2.0 = 1.77%). If the total episode payment amount for this RO participant after applying the trend factor, adjustments, and discount factor was $2,6465.68[28] with an AQS of 88.3 the quality reconciliation quality amount would be $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 will be distributed in the annual lump sum during the reconciliation process.

In response to concerns about the AQS structure, CMS states it will endeavor to calculate individual quality measure scores and an annual AQS as quickly as possible to determine payment adjustments. CMS believes the Model's design serves to incentivize all RO participants to provide high quality care and earn the available incentive payments from the Model in addition to the Advanced APM and MIPs incentives. CMS agrees with a commenter that it is unrealistic to expect RO participants to score 100 percent for all measures but it does not agree with the recommendation to adopt a scoring curve or other adjustments that would offer full credit for performance below a measure's benchmark.

[28] This number was calculated using information in line(j) in Table 5 of the proposed rule.

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

CMS expects the RO Model will qualify as an Advanced APM and an 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. RO Model participants who are APM Entities and eligible clinicians seeking Qualifying APM Participant (QP) status in an Advanced APM must comply with all RO Model requirements to be eligible for Advanced APM incentive payments. RO participants who do not meet the QP thresholds do not qualify for the Advanced APM incentive payments and may be required to report to MIPS as participants in a MIPS APM.

CMS *finalizes its proposal to establish an "individual practitioner list*" under the RO Model (§512.205). This Participation List would be created by CMS and sent to Dual participants and Professional participants upon the start of each performance year. 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 as 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 *finalizes with modifications* several other proposals related to the individual practitioner list. Prior to the start of each PY, CMS will 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. An individual with the authority to legally bind the RO participant must certify the accuracy, completeness, and truthfulness of the list. CMS clarifies that MIPS eligible clinicians identified on the Participation List of an APM Entity participating in a MIPS APM for the performance period are eligible to be scored as part of an APM entity group. If the Dual participant or Professional participant does not verify and certify the individual practitioner list by the specified CMS deadline, the RO participants on the unverified list are not recognized as participants in an APM Entity for purposes of the QPP.

CMS also *finalizes with modifications* its proposal 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 30 days. 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 clarifies that the removal of an individual practitioner from the RO participant's individual practitioner list is effective on the date that the individual ceases to be an individual practitioner as defined in §512.205.

A commenter requested clarification on whether under the RO Model the entire multispecialty practice that currently reports under the MIPS program or just the radiation oncologists would be participating as an Advanced APM. CMS notes that it will provide RO participants with an individual practitioner list for review, modification, and certification. The certified list that

includes only physician radiation oncologists who have reassigned their rights to receive Medicare payment for RT services to the TIN of the RO participant will be used for QP determinations. CMS modified its proposal to use an uncertified list and finalizes that only a certified list will be used. CMS is concerned that using an uncertified list might result in incorrect or unauthorized payments and adjustments under the QPP. RO participants on an uncertified list will not be considered participants in an APM Entity for purposes of the QPP.

CMS disagrees with comments that the annual certification process of the individual practitioner list is very burdensome. CMS believes that 30 days is a sufficient timeframe for RO participants to review and submit correction. CMS does agree that 15 days may be an insufficient period of time to make additions to the list and modifies its proposals to allow for a 30-day period.

To qualify as an Advanced APM, the RO Model must meet certain criteria specified in regulation at 42 CFR 414.1415. CMS discusses how the proposed model meets these criteria.

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 proposed 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 believed 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 specify that an Advanced APM base payment must include at least one outcome measure. CMS stated, 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 stated there currently are no such outcome measures available or applicable.

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 expected 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 stated 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 anticipated 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.

In response to comments requesting clarification about the CEHRT requirements, CMS states it aligns the CEHRT requirements with the regulatory requirements of the QPP which relies on the definition of CEHRT as defined and periodically updated at 42 CFR 414.1305. This definition currently specifies the use of 2105 Edition Base EHR edition and has been certified to the 2015 Edition health IT certification criteria. CMS also believes that certifying an intent to use CEHRT at the beginning of the performance year, as opposed to the end, is appropriate and aligns with requirements in other Advanced APMs.

A few commenters expressed concern regarding the risk involved for participants in the RO Model; some requested CMS redesign the Model to allow for two-sided risk and others suggested CMS should risk levels similar to other APMs or include stop-loss provisions. CMS believes that including RO participants' historical experience in their participant-specific RO payment amount, combined with the low volume opt-out option (discussed in section III.C.3.c in the final rule), minimizes the potential losses that a RO participant may occur. CMS acknowledges these concerns, and adopts a stop-loss limit of 20 percent for RO participants furnishing included RT services in the CBSAs selected for participation on the date this final rule becomes effective (discussed in section III.C.6.e(4) in the final rule). CMS discusses why it believes that the level of risk established for the RO Model, is above the minimum level specified in the generally applicable nominal amount standard established for the QPP. CMS notes that the RO Model does have two-sided risk; participants that provide services more efficiently than the RO episode price yield savings for the participants and those that provide services less efficiently yield losses for the participants.

A commenter requested that CMS assure MIPS eligible clinicians participating in the RO Model that they will qualify for an exemption from MIPS and earn the APM incentive. CMS responds that it has designed the Model to be both an Advanced APM and a MIPS APM and all eligible clinicians participating in the RO Model will have the opportunity to become QPs or Partial QPs based on meeting the relevant payment or patient count thresholds. It acknowledges, however, that not all eligible clinicians in the RO Model will achieve QP status or earn an APM Incentive Payment. CMS notes that based on its actuarial analysis, it believes that most eligible clinicians

will achieve QP status during the course of the RO Model.[29] In addition, eligible clinicians in the RO Model who are MIPS eligible clinicians will be considered participants in a MIPS APM.

MedPAC did not support CMS' proposal that the RO Model would qualify as an Advanced APM because the RO Model did not meet two of MedPAC's principles for advanced APMs. Specifically, MedPAC raised concerns that the RO Model does not meet its principle that clinicians should receive a 5 percent incentive payment only if the eligible entity is successful in controlling cost, improving quality, or both; and the eligible entity should be at financial risk for total Part A and Part B spending. MedPAC also stated that the RO Model does not follow its principle to help move the fee-for-service (FFS) payment system from volume to value, encourage care coordination, and more broadly reform the delivery system. MedPAC disagreed with CMS' decision not to propose any outcome measures and thought that measures similar to the OCM claims-based outcome measures should be considered for the RO Model.

CMS disagrees with MedPAC that the RO Model should not qualify as an Advanced APM and discusses how the Model meets the statutory criteria for APMs and eligible APM Entities established in §1833(Z)(3)(C) and (D) of the Act and codified at 42 CFR 414.1415. CMS discusses how the RO Model meets the three criteria for Advanced APMs: (1) the APM requires use of CEHRT, (2) payments under the APM is based on MIPS-comparable quality measures, and (3) the APM requires participants to assume more than nominal financial risk. CMS also reiterates that it considered using the same OCM outcome measures for the RO Model, but decided it would be difficult to determine whether these outcomes occurred due to complications from RT services, chemotherapy, or other reasons. CMS will continue to explore an appropriate outcome measure for the RO Model. CMS also discusses the applicability of MedPACs principles for Advanced APMs to the RO Model and stresses that the RO Model is specifically testing different pricing methodologies for the RT services provided and not the other costs associated with the beneficiary.

CMS *finalizes its proposals, with modifications*, that effective January 1, 2021, at least one of the quality measures used by the RO Model to base payment will meet at least one of the following criteria: (a) finalized on the MIPS final list of measures; (b) endorsed by a consensus-based entity; or (c) determined by CMS to be evidence-based, reliable, and valid. CMS expects the Model to qualify as both an Advanced APM and a MIPS APM beginning on January 1, 2021. Final CMS determination of Advanced APMs and MIPS APM beginning for the 2021 performance period will be announced on the QPP website (https://qpp.cms.gov).

CMS *finalizes with modifications*, that most APM Entities, with the exception of those RO participants that qualify for the stop-loss provision, will be at risk for all costs associated with RT services, beyond those covered by the participant-specific professional episode payment or the participant-specific technical episode payment. Participants will be at 100 percent risk for all

[29] During the course of Model, CMS expects 83 percent of RO Model physicians to be QP and 9 percent to be partial QPs.

expenditures in excess of the expected amount of expenditures. Based on these finalized provisions, CMS states the RO Model would meet the criteria to be an Advanced APM.

CMS *finalizes with modifications* to use the individual practitioner list to identify the relevant eligible clinicians for making QP determinations and determining those MIPS eligible clinicians who are considered participants in a MIPS APM. CMS clarifies that participants in a MIPS APM are those MIPS eligible clinicians who are identified on a Participation List of an APM Entity participating in a MIPS APM for the performance period.

CMS also *finalizes as proposed* that participants must use CEHRT, that the RO participant must annually certify its intent to use CEHRT during the Model performance period, and that the RO participant will be required to certify its intent to use CEHRT within 30 days of the start of the PY1.

CMS also notes that he following provisions finalized in other sections of the final rule will also apply to any APM Incentive Payments made for eligible clinicians who become QPs through participation in the RO Model:

- Finalized proposals regarding monitoring, audits and record retention, and remedial action, as described in section II.F and III.C.14.
- Finalized proposal in section III.C.10.c, which explain 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.

10. Medicare Program Waivers

CMS proposed 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.

a. Waiver of the Requirement to Apply the Hospital Outpatient Quality Reporting (OQR) Program Payment Reduction

CMS proposed to waive the hospital payment reduction authorized under section 1833(t)(17)(A) of the Act. CMS would not apply the two-percentage point reduction to the OPPS 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.

Final Decision: CMS received no comments and finalizes its proposal as proposed.

b. Waiver of the Requirement to Apply the MIPS Payment Adjustment Factors to Certain RO Model Payments

CMS proposed 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 clinicians' performance on quality measures for a performance. Subjecting an RO participant to payment consequences under MIPS and the Model for potentially the same quality measures could have unintended consequences.

Comments/Responses: Many commenters disagreed with this proposal arguing that it would unfairly penalize clinicians for their efforts to comply with MIPS requirements, particularly in those performance years prior to the RO Model start. CMS agrees with the commenters and upon further consideration it is not finalizing its proposal to waive the MIPS payment adjustment factors for the PC of the RO Model payments. CMS notes that it anticipates that many eligible clinicians in the model will achieve the Qualifying APM Participant (QP) threshold and will be excluded from MIPS, starting in QPP performance year 2021 (payment year 2023).

Final Decision: CMS finalizes its proposal at §512.280(c) with a modification to only waive the MIPS payment adjustment factors for the TC of RO Model payments. It is not finalizing its proposal to waive the MIPS payment adjustment factors for the PC of RO Model payments. If an RO participant does not earn a positive MIPS adjustment, payments for the PC will be reduced by the MACs as they would be outside the RO Model.

c. Waiver of Requirement to Include TC Payments in the Calculation of the APM Incentive Payment Amount

CMS proposed to waive requirements to include TC payments in the 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 was 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.

Comments/Responses: Most commenters disagreed with this proposal arguing that not including the TC in the payment amount used to calculate the APM Incentive Payment would make it very difficult to offset any reduced payments that occur as a result of participation in the RO Model. CMS disagrees with the commenters for several reasons including that the TC payment is not a payment for professional services, but for technical services. CMS is also concerned that inclusion of the TC payment could create an inadvertent incentive for Professional participants to increase TC services furnished in freestanding radiation therapy centers instead of an HOPD and potentially prejudicing the model testing of site neutral payments.

Final Decision: CMS finalizes its proposal at §512.280(d) to exclude the TC payment of the RO Model from the APM Incentive Payment calculation, with a modification to clarify that CMS is waiving the requirements of §414.1450(b) of 42 CFR chapter IV for this purpose.

d. General Payment Waivers

CMS also proposed to waive certain general payment requirements regarding how payments are made to allow the RO Model's prospective episode payment to be fully tested. CMS proposed 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 also believes it was 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.[30] This would apply to nonexcepted off-campus provider-based departments (PBDs); the PFS relativity adjuster 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 adjuster to the RO Model payment and instead would pay them in the same manner as other RO Model participants. CMS believed this waiver was necessary to allow for consistent model evaluation and ensure site neutrality in RO Model payments, which is a key feature of the RO Model.

Final Decision: CMS received no comments on the general payment waivers proposed and therefore finalizes these provisions without modification. After considering public comments, CMS also finalizes an additional waiver of section 1833(t)(2)(H) of the Act. This provision requires separate payment of brachytherapy sources provided in HOPDs.

e. Waiver of Appeals Requirements

CMS proposed to waive section 1869 of the Act specific to claims appeals to the extent otherwise applicable. It proposed 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. CMS noted that if RO participants have general Medicare claims issues, then the RO participants should continue to use the standard CMS

[30] 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 section 1833(t)(21) to the Social Security Act.

claims appeals procedures. CMS also stressed that its proposal does not limit Medicare beneficiaries' right to the claims appeals process under section 1869.

Final Decision: CMS finalizes without modification its proposed waiver of appeals requirements, specifically to waive section 1869 of the Act specific to claims appeals for RO Model claims.

11. Reconciliation Process

CMS proposed 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 to allow time for claims run-out, data collection, reporting, and calculating results.

Comments/Responses: Many commenters expressed concern about the annual reconciliation taking place in August of the following PY, citing issues of health care provider burden, financial hardship, and patient access to care. CMS notes that it made changes elsewhere in the final rule that will likely reduce the financial burden associated with the timing of the reconciliation such as reducing the incorrect payment withhold from 2 percent to 1 percent.

Final Decision: CMS adds a definition at §512.205 for "initial reconciliation," which means the first reconciliation of a PY that occurs as early as August following the applicable PY

CMS also made non-substantive editorial and organizational changes to the regulation text at §512.285. It also notes that it removed language indicating the reconciliation will always occur in August, and instead states that initial reconciliation could occur as early as August as CMS may require additional flexibility. CMS also states that if an RO participant fails to timely pay the full repayment amount, CMS will recoup those funds from any payments otherwise owed by CMS to the RO participants, including Medicare payment for unrelated items and services, and interest will be charged.

a. True-Up Process

CMS also proposed 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.

Final Decision: CMS finalizes its definition of "true-up" with technical modifications to read as follows: "*True-up reconciliation* means the process to calculate additional reconciliation payments or repayment amounts for incomplete episodes and duplicate RT services that are identified after the initial. It also clarifies that that the true-up reconciliation process is only related to the incorrect payment withhold, and it will not conduct a true-up reconciliation for the quality withhold or the patient experience withhold. CMS adds a stop-loss reconciliation amount to the reconciliation process (for those RO participants that have fewer than 60 episodes) at §512.285(f).

b. 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 proposed 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.

Final Decision: CMS finalizes its proposed provisions at §512.285 that the reconciliation process will occur annually, with each RO participant receiving a reconciliation report that indicates the reconciliation payment amount they are due or the repayment amount owed to CMS. Because of the change to the incorrect payment withhold in this final rule from 2 percent to 1 percent CMS provided an updated example reconciliation calculation for a Professional participant in Table 14 (reproduced below), which reflects that change. In this example, the Professional Participant would receive $3,600 from CMS after all adjustments.

Table 14: Example Reconciliation Calculation for a Professional Participant

Professional participant	**Formula**	**Example**
Sum of the episode payment amounts (after trend factor, adjustments, and discount factor have been applied)		$300,000
Total Incorrect Payment Withhold Amount (a_1)	a_1	$3,000
Total Duplicate RT Services Amount (a_2)	a_2	($3,000)
Total Incomplete Episode Amount (a_3)	a_3	($1,500)
Incorrect Episode Payment Reconciliation Amount (a)	$a = a_1 + a_2 + a_3$	($1,500)
Quality Withhold (b_1)	b_1	$6,000
AQS (b_2)	b_2	0.85

Quality Reconciliation Amount (b)	$b = b_1 * b_2$	$5,100
Stop-loss Reconciliation Amount (c)	c	
Reconciliation Payment/(Repayment Amount, if this were to be negative, indicating an amount owed to CMS by the RO participant) (d)	$d = a + b + c$	$3,600

12. Timely Error Notice and Reconsideration Request Processes

CMS proposed 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 noted 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 proposed 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 believed it was 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 believed that such a process would lead to more timely resolution of disputes.

CMS proposed 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 from its experiences with other models, CMS proposed that the first level of the proposed reconsideration process would be a timely error notice. Specifically, CMS proposed 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 noted that this would be subject to the limitations on administrative and judicial review.

CMS proposed 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 proposed 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 proposed to codify this timely error notice policy at §512.290(a).

Comments/Responses: Several commenters suggested additional time (45 days or 90 days) to review reconciliation reports and submit potential errors to CMS. CMS agrees with the commenters that additional time may benefit some RO participants in identifying and understanding calculation errors.

Final Decision. CMS finalizes its proposed timely error notice provisions with a modification of extending the amount of time that RO participants have to submit their timely error notice, which must be received by CMS within 45 days after the issuance of a reconciliation report, at §512.290(a).

b. Reconsideration Review

CMS proposed that the second level of the 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 responding to the RO participant's timely error notice. CMS proposed 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 proposed 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 proposed 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 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 proposed that the determination made by the CMS reconsideration official would be final and binding. This process would be codified at §512.290(b).

Comments/Responses: A few commenters requested additional time for RO participants to submit a reconsideration request. CMS responds that it modified the timeline of the timely error notice deadline but does not believe additional time is needed to submit a reconsideration request.

Final Decision: CMS finalizes its proposed reconsideration review provisions with non-substantive editorial and organizational changes to streamline and improve the clarity of the regulation text at §512.290(b).

13. 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), to evaluate and monitor the RO Model, CMS may require model participants to report certain data. CMS proposed the following data related requirements.

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 (HIPAA) and the Health Information Technology for Economic and Clinical Health (HITECH) Act.

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 proposed 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.

Final Decision: CMS finalizes the provisions at §512.275(a), with modifications to the regulatory text to align the regulatory text with the proposals discussed in the preamble. These modifications specifically add "patient-identifiable derivative data" to the regulatory text.

b. RO Participant Release of Patient De-Identified Information

CMS did 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 HIPAA requirements in 45 CFR 164.514(b).

CMS proposed 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 proposed 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.

Final Decision: CMS finalizes this proposal without modification at §512.275(b).

c. Data Submitted by RO Participants

CMS proposed 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 services 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 proposed to require RO participants to submit 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. It proposed 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.

Comments/Responses: Several commenters requested that comprehensive radiation oncology accreditation standards be used to ensure that the quality and compliance standards are met. A couple of commenters indicated that the proposed annual mandatory survey that CMS may use to request additional information, such as the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status does not have a direct relation to the Model. A commenter further believed that such information may include proprietary information and requested that the data collected by CMS be aggregated and blinded.

In response, CMS agrees with the commenters that accreditation by nationally recognized organizations, such as the ACR, ACRO, and ASTRO, may be an indicator of the overall quality of care provided by a RT provider or RT supplier. CMS notes, however, that it will not use the submission of accreditation status information in lieu of the quality and compliance reporting

requirements. RO participants may volunteer to submit administrative data related to their accreditation status. CMS disagrees with the commenter that additional administrative data does not have a direct relation to the RO Model, but acknowledges the concerns related to proprietary information. CMS is modifying its proposal to make submission of such administrative data optional.

Final Decision: CMS finalizes this proposal with a modification. Requests by CMS for administrative data related to the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status will be optional for RO participants.

d. Data Provided to RO Participants

Thirty days prior to the start of each PY, CMS proposed 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. At 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 proposed 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 proposed 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 proposed 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 if the data has been de-identified in accordance with HIPAA requirements.

Comments/Responses: Commenters requested that CMS provided data on a timelier basis. One commenter suggested that CMS provide participant-specific professional episode payment and participant-specific technical episode payment amounts for each cancer type to RO participants 90 to 180 days prior to the start of the PY rather than the proposed 30 days in advance. CMS replies that it is not feasible to provide this information much sooner as pricing components used to derive the payments are not published until November before the start of the PY for which they would apply. As explained in section III.C.6.c of the final rule and summary, CMS modified its proposed policy and will provide each RO participant its case mix and historical experience adjustments at least 30 days prior to start of PY rather than participant-specific professional and technical episode payment amounts for each cancer type.

Final Decision: CMS finalizes its proposals with the modification that it will provide RO participants with their case mix and historical experience adjustments for the professional and technical components at least thirty (30) days prior to the start of each PY (see regulatory text at § 512.255).

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 42 CFR part 2-compliant authorization from each individual about 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[31], Federal Information Processing Standard 200[32], and NIST Special Publication 800-53[33].

CMS proposed 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.

Final Decision: CMS finalizes its proposed data sharing policies with the modification that requests by CMS for administrative data related to the cost of providing care, frequency of equipment use, EHR vendors, and accreditation status will be optional for the RO participant. CMS codifies these policies at its regulation at §512.275(a)-(b).

14. Monitoring and Compliance

CMS notes in the proposed rule that 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 help ensure that the model is implemented safely and appropriately.

Consistent with §512.150(b), CMS anticipated 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

[31] 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.
[32] 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.
[33] 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.

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. Monitoring for Utilization/Costs and Quality of Care

CMS stated in the proposed rule that it would 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 anticipated 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 stated 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.

CMS stated that RO participants would report data on program activities and beneficiaries consistent with the data collection policies proposed in section III.C.8 of the proposed rule. 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. Monitoring for Model Compliance

CMS detailed the activities it would monitor for model compliance. This included requiring all participants to annually attest that they would use CEHRT in a manner sufficient to meet the requirements. CMS also proposed 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 proposed to codify these RO Model requirements at §512.220(a)(3). CMS stated 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 proposed to codify at §512.220(a)(2) a requirement that 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.

Comments/Responses: Among other comments, several commenters were concerned with the proposed requirement of attesting annually to active participation in a radiation oncology-specific patient safety organization (PSO). They wanted clarification of the PSO requirement and asked whether participation in any PSO could meet the compliance requirement noting that there are fees associated with joining a PSO as well as the time and resources its takes to join. Other commenters expressed concerns with the peer review requirements as being onerous for RO participants, particularly single practitioners and those practicing in underserved areas.

Final Decision: After consideration of these comments, CMS finalizes its proposed policy with modifications. RO participants will be in compliance so long as they annually attest to active participation with any PSO; it is not a requirement that the participant be in a radiation oncology-specific PSO. The PSO requirement will be effective beginning in PY1. For the peer-review requirements, CMS states this will be finalized as proposed with reporting to begin in PY 1. CMS codifies these policies at §§512.150 and 512.220

c. Performance Feedback

CMS proposed 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 stated that the design of and frequency that these reports are provided to participants would be determined in conjunction with the RO Model implementation and monitoring contractor.

Final Decision: CMS received no comments on this proposal and finalizes this policy as proposed.

d. Remedial Action for Non-Compliance

CMS refers readers to section II.J of this final rule for its policies regarding remedial and administrative action.

15. Beneficiary Protections

CMS proposed to require that Professional participants and Dual participants notify each RO beneficiary that they are participating in this RO Model by providing written notice during the RO beneficiary's initial treatment planning session. CMS stated 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 believed 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 proposed that the required RO Model beneficiary notice be exempt from the requirement at §512.120(c)(2), which requires that the model participant include a standard disclaimer statement on all descriptive model materials and activities. CMS proposed these policies at §512.225(c). Beneficiaries with any questions or concerns with their physicians are encouraged to contact CMS using 1–800–MEDICARE, or their local Beneficiary and Family Centered Care-Quality Improvement Organizations (BFCC-QIOs).

Comments/Responses: Commenters recommended that CMS make a concerted effort to educate all beneficiaries who may be impacted by the RO Model about the unique coinsurance requirements inherent to the model's design. They recommended making such information available to beneficiaries on the Medicare.gov website and the *Medicare & You* publication.

CMS replies that RO participants must notify all RO beneficiaries to whom they furnish RT services regarding their cost-sharing responsibilities. Such notice will be provided through the beneficiary notification letter (drafted by CMS which RO participants can personalize with their contact information and logo). It also states that it will consider other ways to provide RO beneficiaries with details about the RO Model.

Final Decision. CMS finalizes its proposed provisions on beneficiary protections with the modification of non-substantive changes to the proposed provisions at §512.225 in the final rule to improve readability. The beneficiary notification requirement will begin in PY1.

16. Evaluation

Under section 1115A(b)(4) of the Act, the Secretary is required to evaluate each model tested by the Innovation Center.

CMS stated in the proposed rule 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 described questions the evaluation may 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?

In the proposed rule, 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 states it would 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.

Comments/Responses: Commenters expressed concern about the possible unforeseen circumstances and unintended consequences from the model. They urged CMS to evaluate the model effects on quality of care and patient access, provider and supplier burden, and the effects of including PBT centers. In response, CMS notes that it will be collecting and analyzing measures of quality and access to care to help assess the RO Model's impact on beneficiaries' outcomes and experience. It also notes that it designed the model to minimize RO participant burden but will be conducting some additional data collection to examine this issue. It also notes

that it may not be able to do certain sub-analyses, such as the effects of including PBT, as it may not have sufficient sample size of RO participants or RO episodes.

Final Decision: CMS finalizes its proposals on evaluation as proposed.

17. Termination of the RO Model

In the proposed rule, CMS stated that the proposed general provisions relating to termination of the Model by CMS would apply to the RO Model. CMS received no comments on the termination of the RO Model. As explained in section II.J. of this final rule, CMS finalizes its proposal to apply §512.165 to the RO Model.

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

a. Overview

CMS stated in the proposed rule that it believes that the RO Model would be compatible with other CMS models and programs but recognized that overlap could exist with other models being tested by the Innovation Center. CMS did not 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 stated that if such adjustments were 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 stated in the proposed rule that it believed there would be potential overlap between the proposed RO Model and ACO initiatives. CMS believed, 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 believed 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 recognized 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 stated it intends to continue to review the potential overlap, and if substantial overlap occurs, it will consider adjusting the RO Model payments through future rulemaking to ensure Medicare retains the discount amount.

Comments/Responses: A few commenters recommended that CMS finalize a policy to exclude beneficiaries aligned to an ACO who receive RT services from attribution to an RO participant under the RO Model. In response, CMS notes that it did not propose to exclude RT practices participating in ACOs from the RO Model. It believes that excluding beneficiaries aligned to

ACOs would be operationally challenging and counter to the incentives under the RO Model and the ACO initiatives.

Final Decision: CMS finalizes its proposed policy to allow ACO-aligned beneficiaries to be attributed to practices participating in the RO Model.

c. Oncology Care Model (OCM)

CMS anticipated 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 made the point in the proposed rule 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.

If 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 proposed 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 proposed 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 stated 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.

Comments/Responses: Many commenters agreed with CMS' proposed approach for accounting for overlap between OCM and the RO Model. Some requested additional details regarding the proration methodology and others wanted CMS to reconsider how the RO Model will overlap with the OCM. A commenter suggested, for example, that CMS use the final discounted amount of the RO Model payment as the payment to the RO participant for purposes of the OCM reconciliation calculation.

In its reply, CMS states that it anticipates that roughly 30 percent of OCM practices that provide RT services will participate in the RO Model. Because OCM is a total cost of care model, any changes in the cost of RT services during an OCM episode could affect OCM episode expenditures. Due to this potential overlap. CMS proposed a prorated approach to ensure there is no double counting of savings or payment of the withhold amounts between the two models. It refers readers to its description of the proration methodology in the proposed rule (84 FR 34535) for more details about how it is calculated. It notes that it believes a process to allocate exact amounts paid to the RO participants when the OCM and the RO Model have different reconciliation timelines would be operationally complex.

Final Decision: CMS finalizes its proposed approach for addressing the overlap between the OCM and the RO Model as proposed.

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 noted in the proposed rule 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 their 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 may examine this issue in future rulemaking based on comments received.

IV. End-Stage Renal Disease (ESRD) Treatment Choices Model[34,35,36]

A. Introduction and Background

1. Rationale for Testing the Proposed ETC Model

Prior to proposing the ETC Model, CMS conducted an extensive review of the literature on ESRD treatment. CMS states that healthcare providers and patients view home dialysis and kidney transplantation as preferable treatment alternatives for adults with ESRD. CMS notes that ESRD treatment in the United States (U.S.), however, is dominated by hemodialysis provided to outpatients in ESRD facilities (in-center dialysis). Treatment is directed by clinicians (termed Managing Clinicians) to whom Medicare pays a monthly capitation payment (MCP). Through ETC Model testing, CMS intends to assess whether 1) adjusting FFS payments to facilities and clinicians treating ESRD patients will increase home dialysis and transplantation rates and 2) increasing rates will improve and/or maintain the quality of ESRD patient care while reducing Medicare program expenditures.

CMS received over 100 comment submissions. Commenters on the ETC Model test rationale voiced support but also expressed skepticism that payment adjustments will overcome the barriers to home dialysis and transplantation uptake (e.g., immunologic barriers, housing insecurity).

2. Benefits of And Barriers to Home Dialysis

CMS notes that home dialysis modalities include hemodialysis (HD) and peritoneal dialysis (PD); the latter is rarely provided outside of the home setting. CMS observes that the proportion of home dialysis patients (versus in-center dialysis) in the U.S. has declined over time, falling from over 40 percent in 1973 to 16 percent by 1988 and below 10 percent by 2012.[37] CMS also observes that U.S. home dialysis rates lag those of other developed countries (e.g., Hong Kong at 74 percent, Canada at 25 percent).[38] CMS discusses reports suggesting that overall medical expenditures for home dialysis are reduced and that survival and quality of life are increased compared to in-center dialysis. CMS notes that factors described as contributors to low uptake of home dialysis in the U.S. include educational barriers, necessity for home care partner support, requirement for a monthly in-home clinician visit, and the philosophies and business practices of dialysis providers.

[34] In this summary, kidney transplantation is used to mean both kidney-only and kidney transplant when part of any multi-organ transplantation procedure, unless otherwise noted.
[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] Chronic kidney disease stages (1-5) are assigned based on a patient's estimated glomerular filtration rate (eGFR).
[37] United States Government Accountability Office. End Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis (GAO-16-125). October 2015
[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

Comments were numerous and diverse, including: 1) comparing home dialysis in the U.S. with other countries is inappropriate given demographic and health system variations; 2) increased home dialysis uptake could create economies of scale for supplies and logistics and spur new technology development; and 3) barriers to home dialysis also include burdensome Medicare home dialysis program certification requirements. CMS responds that: 1) comparisons with other countries were provided for context and the ETC Model is specifically designed for the U.S. and its Medicare services market; 2) ETC Model benchmarking and scoring methodologies account for home dialysis supply and logistical issues; and 3) CMS is not waiving the home dialysis certification requirements in order to preserve patient health and safety.

3. Benefits of And Barriers to Transplantation

CMS observes that U.S. transplantation rates lag those of other developed countries, ranking 39th of 61 countries reporting in 2016.[39] CMS discusses evidence suggesting that mortality is lowered and quality of life is improved by transplantation compared to chronic dialysis, and that overall medical expenditures are less for transplant recipients. CMS notes that barriers to transplantation are numerous but the main barrier is the supply of available organs. CMS further notes that a successful transplant represents lost revenue for the beneficiary's ESRD facility, and, to a lesser degree, the Managing Clinician.

Commenters supported the desirability of transplantation as the best treatment option for most ESRD patients but objected to comparisons of U.S. transplantation rates with other countries. Commenters concurred that donor organ availability is the key barrier to transplantation. CMS again responds that comparison with other countries is provided for context and the ETC Model is designed specifically for the U.S. chronic kidney disease (CKD) population. CMS notes that the ETC Learning Collaborative to be implemented as part of the model is expected to increase the supply and use of deceased donor organs.

4. Addressing Care Deficits Through the ETC Model

Home dialysis and transplantation are supported by patients as preferred ESRD treatment options yet U.S. utilization rates for these options appear to be low. The ETC Model addresses these gaps through two types of performance adjustments to facility and clinician payments, the Home Dialysis Payment Adjustment (HDPA) and the Performance Payment Adjustment (PPA). Beneficiary education about ESRD treatment options would be made more accessible through revisions to Medicare's Kidney Disease Education (KDE) benefit, potentially increasing beneficiary interest in home dialysis and transplantation.

Commenters generally supported the ETC Model goals. Some expressed reservations about or opposition to the model, including:

- Barriers not or incompletely addressed, such as supply of trained home dialysis staff, the unique structure of the dialysis market, and incenting consideration of patient choice.

[39] United States Renal Data System, Annual Data Report, 2018. Volume 2. Chapter 11 International Comparisons.

- Harm caused by the model's financial risks for small dialysis organizations and rural ESRD facilities;
- Methodological limitations leading to unintended consequences and adverse outcomes;
- Net result being payment reductions for all dialysis providers; and
- Preference for alternative approaches, including voluntary models that incent care coordination and collaboration.

CMS responds that the ETC Model is one part of a larger HHS effort to improve care of CKD beneficiaries. CMS refers commenters to ETC Model provision details as finalized in subsequent sections of the rule. Finally, CMS states that suggestions not related to the ETC Model itself are out-of-scope for this rule but may be considered in the future.

5. Medicare ESRD Program

CMS provides history and background information to facilitate understanding of the ETC Model's goals, design, and provisions. In 1972, Medicare Part A and Part B eligibility was extended to individuals with ESRD regardless of age and was amended in 1978 to include specific payments for 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. Section 1881(c)(6) of the Act explicitly states "It is the intent of the Congress that the maximum practical number of patients who are medically, socially, and psychologically suitable candidates for home dialysis or transplantation should be so treated".

Currently, most 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 for kidney transplants. 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. Part A covers dialysis for hospital inpatients and inpatient services for covered kidney transplants. Kidney donor care is provided through Parts A and B. ESRD coverage under Part C has been limited, primarily available to beneficiaries enrolled in MA plans prior to their ESRD diagnoses. However, beginning in 2021, the 21st Century Cures Act allows already-diagnosed ESRD beneficiaries to enroll in MA plans. Part D coverage includes renal dialysis drugs available only in oral formulations.

a. ESRD Prospective Payment System (PPS) under Medicare Part B

Beginning with 1983, payment to outpatient dialysis facilities was based on a "composite rate" that bundled payments for routine costs, recurring ESRD-related drugs, laboratory tests, and items and services generally applicable to all dialysis options. The composite rate payment was fully replaced by the ESRD PPS beginning in 2014. 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 patient-level (case mix variables) and facility-level (wage-index, low-volume, rural) adjustments. Added payments are made for high-cost outlier beneficiaries, home training,[40] and transitional drugs.[41] A separate add-on adjustment, Transitional Payment for New and Innovative Equipment and Supplies (TPNIES), was implemented beginning with the CY 2020 ESRD PPS. PPS payments are updated annually using the ESRD market basket, subject to a productivity adjustment. Under the ESRD Quality Incentive Program (QIP), facility payments may be reduced further by up to two percent for failure to meet specified quality measure targets.

b. Monthly Capitation Payment (MCP)

Outpatient maintenance dialysis (home or in-center) typically requires several recurring services to be furnished by a physician or other qualified healthcare professional (e.g., adjusting the dialyzing cycle). Payment is made directly by Medicare to the billing physician as a single monthly capitated payment, termed the MCP. The practitioner submits a claim using a set of age-specific CPT ESRD codes (90951-90970), which also specify the number of visits furnished per month. The MCP varies with number of physician visits per month for in-facility dialysis but does not change with number of visits for in-home dialysis.

c. Kidney Disease Education (KDE) Benefit

The KDE benefit was added under Part B for beneficiaries with Stage 4 CKD beginning in 2010. Specified educational topics, including ESRD modality choices, are to be covered in six 1-hour sessions furnished by a physician, physician assistant, nurse practitioner, or clinical nurse specialist (§410.48). An outcome assessment of how well the beneficiary is prepared to make informed treatment decisions must be included in one session. Utilization of the KDE benefit has been very low, under two percent. The statutory restriction to Stage 4 beneficiaries and the limits on the provider type furnishing KDE have been suggested as barriers to KDE uptake.

d. CMS Efforts to Support Dialysis Modality Choices

CMS describes recent actions taken to support beneficiary choice of dialysis modality.

- Transplant centers applying for Medicare reapproval are no longer required to submit clinical experience, outcomes, and other data; this requirement led some centers to avoid certain beneficiaries as potential recipients and to decline use of some available organs.
- The measure "Percentage of Prevalent Patients Waitlisted (PPPW)" has been added to the ESRD QIP beginning with performance year 2022.

CMS also describes alternative payment models (APMs) targeting CKD beneficiary care. The Comprehensive ESRD Care (CEC) model test began in 2015 and will run through March 31, 2021. The model's ESRD Seamless Care Organization (ESCO) design incorporates an

[40] Facilities do not receive the home dialysis training adjustment during the first four months of dialysis. During the latter months, facilities receive a separate dialysis initiation payment.
[41] 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.

accountable care organization (ACO) structure; participation is voluntary and several risk tracks are available. The new Kidney Care Choices (KCC) model builds upon the CEC framework but adds Stage 4 CKD beneficiaries. The voluntary model includes several participation options (e.g., capitation, total cost of care accountability) and a bonus to participants for successful kidney transplants. The first performance year for the first cohort of KCC participants is scheduled to begin April 1, 2021 and the model test is set to end December 31, 2023.

B. ETC Model Regulations

1. Model Test Implementation Timeline (§512.120)

CMS proposed to implement the model test by applying the proposed payment adjustments to claims with a claim through date on or after January 1, 2020 and on or before June 30, 2026; CMS also considered a start date of April 1, 2020 for applying payment adjustments. Most commenters recommended delays of 6-12 months, citing insufficient time for participants to plan and implement care redesign and to start or expand their home dialysis efforts. Other suggested strategies included varying start dates by participant groups (e.g., large dialysis organizations), separate model tests for home dialysis and transplantation payment adjustments, deferred initiation of downside financial risk for all participants, shortening the model's duration to 3 years plus subsequent optional years, and reducing the number of required participants.

CMS agrees that participants would require more preparation time than proposed; a revised start date of July 1, 2020 was under consideration when the COVID-19 public health emergency (PHE) was declared and delayed the release of this final rule. Given the ongoing effects of the PHE on beneficiaries and healthcare providers, CMS finalizes a start date for the ETC Model of January 1, 2021. All time intervals of the model will remain the same length as proposed but will begin and end 12 months later than proposed. CMS notes that participants will have over 90 days to prepare and believes such time to be sufficient. CMS also notes that modifications are being finalized to multiple ETC Model provisions in response to comments received, as discussed elsewhere in the rule. CMS adds that shortening the model test and reducing the participant numbers would reduce the likelihood of generalizable, reliable results. Finally, to facilitate claims processing, CMS replaces the claim through date with the claim date of service for use to determine whether ETC Model payment adjustments apply to a claim.

2. Mandatory Participation (§512.325)

CMS proposed mandatory ETC Model participation for all Managing Clinicians and ESRD facilities in specified locations selected by CMS, with the unit of selection being Hospital Referral Region (HRR), to be operationalized using the definitions below.

- *ESRD facility:* an independent facility or a hospital-based provider of services, including facilities that have a self-care dialysis unit that furnish only self-dialysis services and meets the supervision requirements, and that furnishes institutional dialysis services and supplies (same definition as used for ESRD PPS payment, see §413.171).
- *Managing Clinician:* a Medicare-enrolled physician or non-physician practitioner, who furnishes and bills the MCP for managing one or more adult ESRD Beneficiary.

- *Hospital Referral Regions (HRRs):* regional markets for tertiary medical care derived from Medicare claims data as defined by the Dartmouth Atlas Project at https://www.dartmouthatlas.org/.
- *Selected Geographic Area(s):* HRR(s) selected by CMS for purposes of selecting ESRD facilities and Managing Clinicians required to participate as ETC Model participants.
- *Comparison Geographic Area(s):* HRR(s) that are not Selected Geographic Area(s).

Many commenters opposed mandatory participation for facilities and clinicians, stating that the mandatory model exceeds the Innovation Center's testing authority; the size and scope of the ETC Model represents payment policy change rather than model testing; and the model's requirements will reduce facility and clinician payments and have unintended consequences (e.g., market consolidation). Others added that mandatory models undermine participation in voluntary models. Some commenters supported testing the ETC Model on a smaller scale, with an opt-in participation option for providers from Comparison Geographic Areas, or on a voluntary basis.

CMS responds that a mandatory model structure is necessary to involve a sufficiently large and representative sample of facilities and clinicians to produce valid, reliable, and generalizable test results, particularly given the low frequency of kidney transplants. The mandatory structure also facilitates evaluation of model results to those of a contemporaneous comparison group. CMS states that the Innovation Center's testing authority combined with that of the Secretary to establish regulations for the administration of the Medicare program more than suffices to allow mandatory model testing. CMS does not anticipate adverse effects of the ETC Model test such as market consolidation but will closely monitor the model's impact and respond appropriately to any adverse outcomes (e.g., model modification or termination). CMS notes that voluntary models are subject to selection bias, such as preferential participation by high-performing groups, that would reduce the generalizability of the ETC Model test results. CMS concludes by noting the January 2021 start date for the voluntary Kidney Care Choices (KCC) model designed to care for Stage 4 and 5 CKD beneficiaries through an ESCO-like framework, and describing the synchronous KCC model test as complementary to the ETC Model test.

CMS finalizes that participation in the ETC Model is mandatory as proposed for selected ESRD facilities and clinicians. CMS also finalizes the related definitions as proposed, modified by the addition that Managing Clinicians will be identified by their National Provider Identifiers (NPIs), and incorporating several technical changes (e.g., capitalization).

3. Geographic Areas (§§512.310 and 512.325)

CMS proposed to randomly select geographic areas as locations for identifying mandatory ETC Model participants, with stratification by Census-defined regions (Northeast, South, Midwest, and West), and further proposed Hospital Referral Region as the geographic selection unit to best capture the tertiary care patterns associated with ESRD treatment.[42] To facilitate Maryland's

[42] An HRR spanning two or more census regions would be assigned to the region containing the HRR's associated state (e.g., the Rapid City, SD HRR spans the Midwest and West regions and is assigned to the Midwest region).

ongoing Total Cost of Care model test, CMS further proposed that all HRRs with over 20 percent of component zip codes located in Maryland would be selected for ETC testing. Finally, based on initial statistical power calculations and forecasts of home dialysis and transplantation rates by the Office of the Actuary (OACT), CMS proposed to compel participation in 50 percent of the 306 HRRs that comprise the 50 states and the District of Columbia.[43] The residual HRRs would serve as the Comparison Geographic Areas for model evaluation and benchmarking. Large sample sizes and a contemporaneous comparison group would mitigate the effects on test results of unanticipated and unevenly distributed cofactors.

Many commenters voiced opposition to one or more geographic area provisions of the model. The large sample size, all facilities and clinicians within 50 percent of the HRRs, garnered the most opposition. Commenters postulated care disruption and unintended consequences that would undermine the integrity of the model test and especially harm smaller providers. CMS believes that such concerns are mitigated by the model's delayed start date, benchmarking and scoring methodology, and low-volume exclusions from the downside financial risk of the PPA. CMS notes that the sample size is driven by statistical power calculations and expected changes in transplantation rates. Modifications made to the transplantation rate performance components (such as including transplant waitlisting, discussed elsewhere in the rule) caused CMS to repeat the power calculations and were found to enable sample size reduction to 30 percent of HRRs.

Commenters also expressed concern that common facility ownership within and across regions would facilitate spillover effects from the selected geographic areas to the comparison areas and confound model test results. CMS notes, however, the probability that facilities and Managing Clinicians will each treat beneficiaries in both selected and comparison geographic areas, facilitating spillover effects regardless of the geographic unit of selection for model participation. Common ownership could also lead national dialysis providers to vary resource allocation or otherwise change behaviors in their facilities chosen as participants versus those not selected. CMS shares these concerns and will monitor the outcome measure variations among facilities with common ownership. Covariate-based constrained randomization was suggested by some commenters in place of region-based stratified randomization. CMS disagrees and adds that formal model evaluation will include propensity scoring. CMS also disagreed with a suggestion for oversampling regions with low home dialysis and transplant rates, since targeted sampling could interfere with generalizability of the model test results.

Commenters strongly recommended that participants should be made aware of their selection at least 90 days via release of the Selected Geographic Areas list prior to the ETC Model test start date. CMS confirms that the list purposefully was not released with the proposed rule to avoid receiving model feedback only from selected participants. The list is being released with this final rule, allowing for slightly more than 90 days until the model begins testing January 1, 2021. Commenters expressed concern that entities with participants in both selected and comparison geographic areas will be incented to manipulate model benchmarking by minimizing home dialysis and transplantation rates in comparison areas, improving performance in selected areas.

[43] HRRs were not constructed for the U.S. Territories and those locations are excluded from testing.

CMS responds that several features of the proposed achievement benchmarking methodology would mitigate such risk. For example, achievement benchmarks for the first 3 measurement years (MYs) would include performance data from prior to the model start date that could not be manipulated retrospectively by selected participants (i.e., after learning of their selection). CMS also notes their intention to increase future MY achievement benchmarks through rulemaking to rates above those observed in comparison areas.

Several commenters questioned whether HRRs are the ideal basis for ETC Model participant selection and alternatives were suggested (e.g., Medicare Advantage plan market areas, organ procurement organization donation service areas). CMS responds that the multiple actors involved in ESRD patient care and their associated distinct geographic service areas preclude a single ideal participant selection unit. CMS restates its support for HRRs as the best available approximation of ESRD care patterns and notes that the proposed aggregation methodology incorporated into ETC participant performance assessment should mitigate geographic effects. CMS further notes that the attribution of beneficiaries to ETC participants in one-month increments would minimize impacts of beneficiary movement between HRRs (e.g., snowbirds).

CMS concludes by finalizing:

- The proposed definitions of Selected and Comparison Geographic Areas (with modified capitalization);
- The proposed definition of HRRs, with the clarification that 2017 HRRs will be used for the duration of the ETC Model test; and
- The proportion of HRRs randomly selected for mandatory ETC Model testing to be 30 percent rather than 50 percent as proposed.

A list of the HRRs selected for mandatory ETC participation is available for download from https://innovation.cms.gov/innovation-models/esrd-treatment-choices-model.

4. Other Participant Selection Issues (§§512.310 and 512.325)

All ESRD facilities located within Selected Geographic Areas would be required to participate in the ETC Model test. Facility location would be determined by its practice location address as listed in Medicare's Provider Enrollment, Chain, and Ownership System (PECOS). Commenters suggested that facilities owned by small dialysis organizations should be excluded and offered options for exclusion criteria (e.g., fewer than 100 patients in a market area). Others recommended that only facilities currently certified to provide home dialysis should be selected or supported an unrestricted opt-out option for facilities that decide they cannot support home dialysis. CMS disagrees, desiring that the ETC Model test involve the entire spectrum of facilities and dialysis organizations to ensure generalizable results.

All Managing Clinicians located within Selected Geographic Areas would be required to participate in the ETC Model test. Clinician location would be based on the practice location listed in PECOS from which the clinician bills a plurality of MCP claims. CMS disagrees with a

suggestion to substitute beneficiary dialysis locations for clinician practice locations as confusing and more complex. CMS clarifies that clinicians would be selected based on their locations as individuals rather than the locations of their practices. However, performances of clinicians who share a Tax Identification Number (TIN) for billing would be aggregated for PPA calculations.

Finally, commenters suggested that transplant providers should be added as required ETC Model participants, including transplant centers, transplant physicians and surgeons, organ procurement organizations (OPOs), and donor hospitals. CMS acknowledges the importance of transplant providers to increasing transplant utilization but declines to add them to the model because the model would establish a learning collaborative for transplant centers and OPOs; the model addresses home dialysis not just transplantation rates; and other activities are being supported by CMS to increase organ availability (e.g., expanding reimbursable expenses for living organ donors.

CMS concludes by finalizing:

- The proposed definition of ETC Participant;
- The requirement for all Medicare-certified ESRD facilities located within a Selected Geographic Area to participate in the model, without modification; and
- The requirement for all Medicare-enrolled Managing Clinicians located within a Selected Geographic Area to participate in the model, without modification.

5. Home Dialysis Payment Adjustment (HDPA)

a. General Considerations

The Home Dialysis Payment Adjustment, the first of two payment adjustments proposed by CMS as part of the ETC Model, is designed to increase uptake of home dialysis. The adjustment would separately but similarly increase payments to the two types of model participants, clinician and facility and would be made only to home dialysis related services. CMS proposes to define the Clinician HDPA as an adjustment to the MCP when billed by a Managing Clinician furnishing home dialysis management and the Facility HDPA as an adjustment to the Adjusted ESRD PPS per Treatment Base Rate when an ESRD facility provides home dialysis services.

As proposed, the HDPA adjustments would be applicable to claims with claim through dates that fall within the first three years of the ETC Model test (2021-2023). The adjustments would be positive (increase payments) and applied to eligible payments for all ETC Model participants. The magnitude of the HDPA would decline over time from 3 percent to 1 percent. The HDPA's duration would overlap with that of the model's Performance Payment Adjustment (PPA), discussed in more detail below. CMS proposes that HDPA adjustments would be made to Medicare amounts paid so as not to increase beneficiary cost sharing and would apply regardless of whether Medicare functions as the primary or a secondary payer of home dialysis services.

Most commenters were supportive of the HDPA as defined and its applicability to all ETC Model participants, including when Medicare functions as a secondary payer, and agreed with

making the adjustments to Medicare amounts paid so as to avoid increased beneficiary cost sharing. A recommendation was made to apply the HDPA to vascular access procedures that CMS rejects as outside of the ETC Model's home dialysis focus. A request was received to apply the HDPA to all ESRD providers, not just model participants. CMS declines, as the ETC Model test seeks to measure the effect of incenting home dialysis utilization through payments made to model participants but not to the comparison group.

Commenters recommended increasing the duration of the HDPA by varying lengths (e.g., throughout the model test period), eliminating or slowing the tapering of the adjustment percentage, or setting other HDPA application parameters (e.g., a prerequisite performance benchmark, exclusion of large dialysis organizations (LDOs). CMS declines, viewing the proposed adjustment tapering and the overlapping design of the HDPA (one-sided, positive only) with the PPA (two-sided, positive or negative) as a means to facilitate a smooth transition from process-based to outcomes-based incentives.

CMS agrees with commenters that participants who have home dialysis programs already underway initially will benefit more from the HDPA than those not currently offering home dialysis but expects HDPA availability to quickly stimulate new home dialysis program development. Multiple commenters described the challenges and expenses associated with starting up or expanding a home dialysis program and suggest that these are not fully captured through the HDPA, and suggested higher percentages. CMS responds that the magnitude and duration of the HDPA should be adequate to incent home dialysis program initiation or expansion. Commenters recommended varying the HDPA for some provider subsets (e.g., large dialysis organization (LDOs), small or rural entities). CMS rejects exclusion of provider subsets, noting that increased payments due to the HDPA are equally available to all participants, and to preserve the generalizability of the model test and its results. Concerns were voiced about various possibilities for "gaming" HDPA application; CMS responds that the model's attribution rules and home dialysis rate formulas will mitigate gaming.

CMS concludes by finalizing the definitions, applicability, magnitude, and duration of the HDPA as proposed.[44] CMS updates and finalizes the schedule for HDPA application to reflect the delayed start of the ETC Model, shown below as Table 11.a from the rule.

TABLE 11.a: HOME DIALYSIS PAYMENT ADJUSTMENT (HDPA) SCHEDULE

	CY 2021	CY 2022	CY 2023
Magnitude of Payment Adjustment	+3%	+2%	+1%

[44] A technical formatting change is made (capitalization of all terms) to the HDPA, Clinician HDPA, and Facility HDPA in all relevant regulation sections.

b. Facility HDPA (§512.340)

CMS proposed 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 when 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.[45]

$$\begin{aligned} &ESRD\ PPS\ Per\ Treatment\ Payment\ Amount,\ Current \\ &\quad = (Adjusted\ ESRD\ PPS\ Base\ Rate + Training\ Add\ On + TDAPA)^{46} \\ &\qquad * ESRD\ QIP\ Factor \\ &\qquad + Outlier\ Payment * ESRD\ QIP\ Factor \end{aligned}$$

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

Many commenters supported the HDPA but recommended its application to the training add-on payment since that payment is specific to home dialysis, and to recognize claims with condition code 73, used to indicated home dialysis training, under the Facility HDPA. CMS declines, stating a desire to increase use of home dialysis rather than specifically incent home dialysis training. Some commenters recommended HDPA application to the TDAPA; CMS disagrees as the HDPA is unrelated to new drug development and that the HDPA offers sufficient incentive without TDAPA inclusion.

CMS finalizes the Facility HDPA as proposed with modifications:

- Replacing the claim through date with the date of service to facilitate claims processing;
- Changing the eligible claim's age description to age 18 "before the first day of the month" to facilitate claims processing;
- Removing condition code 75, as the code is no longer valid; and
- Removing condition 80 describing home dialysis when home is a nursing facility, as beneficiaries who reside in or receive dialysis services in a SNF or nursing facility are being excluded from attribution to ETC Model participants (discussed further below).

CMS notes that the CY 2020 ESRD PPS final rule (84 FR 60648) appeared after the ETC Model was proposed; the ESRD PPS final rule created a new payment adjustment to the per treatment rate for new and innovative equipment and supplies (TPNIES). Consistent with excluding the

[45] The adjusted base rate incorporates patient-level (e.g., case mix) and facility-level (e.g., wage index) factors.
[46] The training add-on provides payment for education of beneficiaries (and their care partners) specific to home dialysis procedures. 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.

TDAPA from the Facility HDPA, CMS also finalizes exclusion of the TPNIES. The finalized Facility HDPA formula is shown below.

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

c. Clinician HDPA (§512.345)

CMS proposed 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) and the beneficiary is 18 years or older for the entire month of the claim. These two CPT codes together describe all MCP claims for ESRD beneficiaries age 18 or older who receive home-dialysis services. 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 for dialysis management services) but judged the proposed incentive for home dialysis to be sufficient. CMS also proposed to define the MCP under this model as the monthly capitated payment made for each ESRD beneficiary to cover all routine professional services related to treatment of the patient's renal condition furnished by a physician or non-physician practitioner

A commenter requested that payments for physician services for self-dialysis training of patients be increased during the ETC Model test period. Self-dialysis generally refers to the circumstance in which the patient or care partner carries out some steps (e.g., hooking up to and coming off from the dialysis machine) during a treatment session that most often occurs in a dialysis facility, whereas all steps are performed by the patient (and care partner) during home dialysis. CMS declines the request but notes that self-dialysis usage will be considered during the calculation of home dialysis rates. Some commenters stated the Clinician HDPA amount is insufficient to bridge the gap between the MCP for in-center dialysis and home dialysis. CMS declines to equalize the two MCPs, stating that the Clinician HDPA is sufficient to support clinician care of the anticipated higher number of home dialysis patients and that the costs of managing a home dialysis patient may be reduced compared to an in-center dialysis patient.

CMS finalizes the Clinician HDPA as proposed with modifications:

- Replacing claim through date with date of service to facilitate claims processing; and
- Changing the eligible claim's age description to age 18 "before the first day of the month" to facilitate claims processing.

6. Performance Payment Adjustment (PPA)

a. General Considerations

The Performance Payment Adjustment (PPA) is designed to incent ETC Model participants to focus on care delivery strategies that could increase the home dialysis and transplantation rates in their own ESRD beneficiary populations. The PPA percentage can be positive or negative and the potential magnitude of the adjustment would increase over the duration of the model test. CMS proposes two types of PPAs: the Clinician PPA would be applied to a Managing Clinician's MCP and the Facility PPA would be applied to a facility's Adjusted ESRD PPS Per Treatment Base Rate. Each participant's PPA would be determined based on a Modality Performance Score (MPS) that is derived by comparing the participant's home dialysis and transplantation rates for a 12-month Measurement Year (MY) to predefined benchmarks.

After MY1, each subsequent MY overlaps with its preceding and following MYs until the model concludes with MY10 (e.g., MY3 includes the second half of MY2 and the first half of MY4). The MY overlap results in periodic updating of each participant's PPA percentage. PPAs would be applied to clinician and facility payments during a 6-month PPA Period that begins 6 months after the end of its corresponding MY. The first PPA period would not begin until the middle of the second year of the model test and the final PPA period would end 12 months after the end of the final MY. The PPA, therefore, would run concurrently with the HDPA for 18 months, starting with MY4 and ending with MY6 (see Table 12.a at the end of this summary section).

CMS received numerous comments objecting to the proposed inclusion of transplant rates in the MPS and PPA calculations, stating that transplant rates are largely outside of the control of ETC Model participants given the shortage of donor kidneys. Multiple commenters recommended the substitution of transplant waitlisting rate for transplantation rate, since patient education about transplantation and some parts of the waitlisting process clearly are within the purview of model participants. Some suggested eliminating the transplant rate entirely from PPA-related calculations, creation of a blended rate for home dialysis and transplantation, and basing the PPA on established, NQF-endorsed, publicly reported ESRD-related measures. Other suggestions included adding a shared decision-making measure to the model and counting patients placed by participants on a defined ESRD patient care support pathway toward the home dialysis or transplant rate. Concern was also expressed about the complexity of the multi-step, multifactorial PPA calculations.

CMS responds that incorporating a performance measure that is clearly linked to transplantation into the PPA determination is vital to incent the model's desired outcome of increased transplant rates. CMS agrees with commenters that ETC Model participants have greater control over waitlisting for transplantation than over deceased donor transplantation rates. CMS also notes the considerable potential influence of model participants on the living donor transplant process, which is not primarily rate-limited by organ availability. In response to feedback received, CMS indicates their plan to remove deceased donor transplants from PPA-related calculations (discussed further later in the rule and this summary). Living donor transplants, including

preemptive transplants, will be retained and a transplant waitlisting measure added. (Pre-emptive kidney transplantation occurs when a CKD patient receives a living donor kidney prior to beginning any modality of dialysis.)

A commenter recommended CMS expand transplant-related calculations to include any instance in which a kidney is transplanted, whether alone or in combination with any other donated organ, rather than just kidney or kidney-pancreas procedures. CMS agrees and finalizes a definition of kidney transplant to mean alone or in conjunction with any other organ at §512.310. CMS received no comments upon the proposed definitions for PPA, Clinician PPA, Facility PPA, MY, and PPA Period and finalizes them without modification. The definition for MPS is finalized with a technical modification to correct a cross-reference error. The schedule of MYs and PPA periods is finalized as proposed with modification to reflect the newly finalized model start date of January 1, 2021, shown below in Table 12.a.

TABLE 12.a: ETC MODEL SCHEDULE OF MEASUREMENT YEARS FOR HOME DIALYSIS AND PERFORMANCE PAYMENT ADJUSTMENT PERIODS*

Applicability Starts	HDPA PERIOD	MY	PPA PERIOD
Beginning CY 2021	1/1/2021 – 12/31/2021	MY1 – 1/1/2021 through 12/31/2021	Period 1 – 7/1/2022 through 12/31/2022
		MY2 – 7/1/2021 through 6/30/2022	Period 2 – 1/1/2023 through 6/30/2023
Beginning CY 2022	1/1/2022 – 12/31/2022	MY3 – 1/1/2022 through 12/31/2022	Period 3 – 7/1/2023 through 12/31/2023
		MY4 – 7/1/2022 through 6/30/2023	Period 4 – 1/1/2024 through 6/30/2024
Beginning CY 2023	1/1/2023 – 12/31/2023	MY5 – 1/1/2023 through 12/31/2023	Period 5 – 7/1/2024 through 12/31/2024
		MY6 – 7/1/2023 through 6/30/2024	Period 6 – 1/1/2025 through 6/30/2025
Beginning CY 2024	Not available	MY7 – 1/1/2024 through 12/31/2024	Period 7 – 7/1/2025 through 12/31/2025
		MY8 – 7/1/2024 through 6/30/2025	Period 8 – 1/1/2026 through 6/30/2026
Beginning CY 2025	Not available	MY9 – 1/1/2025 through 6/30/2026	Period 9 – 7/1/2026 through 12/31/2026
		MY10 – 7/1/2025 through 6/30/2026	Period 10 – 1/1/2027 through 6/30/2027

*Recreated by HPA from the rule with modification

[a] HDPA Home Dialysis Payment Adjustment

[b] MY Measurement Year

[c] PPA Performance Payment Adjustment

b. Beneficiary Attribution and Exclusions (§512.360)

(1) Attribution: General Considerations

CMS proposed to attribute ESRD beneficiaries for each month of any 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 any month. CMS proposed attribution on a monthly rather than annual basis to more precisely capture changes in patient relationships with facilities and clinicians. CMS further proposed to provide participants with lists of their attributed beneficiaries once attribution is completed after the end of each MY. Prospective attribution before the start of each MY was considered but rejected given beneficiary attrition through death and transplantation throughout the MY.

CMS proposed to attribute eligible beneficiaries to the facilities at which they received the plurality of dialysis treatments for the month and to the clinician who submitted an MCP claim for that month. CMS also proposed to attribute "pre-emptive transplant beneficiaries", those receiving kidney transplants before ever starting any form of dialysis, to Managing Clinicians but not to the model's ESRD Facilities. The pre-emptive transplant beneficiary would be attributed, for all months between the start of the MY and the month of the transplant, to the clinician submitting the most claims between the start of the MY and the transplant month.

Commenters generally were supportive and CMS finalizes their general attribution proposals with two modifications. First, the definition of ESRD beneficiary is clarified to include transplant recipients who have returned to chronic maintenance dialysis. Second, CMS refines the attribution of preemptive transplant recipients to include only living donor transplants (and not deceased donor transplants) for consistency with the transplantation rate as finalized (discussed later in the rule and this summary). Specifically, only those preemptive transplant beneficiaries receiving kidneys from living organ donors will be attributed to Managing Clinicians and only for the purpose of measuring transplant rate performance.

(2) Exclusions

CMS proposed 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.

Commenters varied in their support for exclusions, from support for all proposed to recommending there be none. CMS states that the proposed exclusions generally were intended to facilitate accurate PPA calculations by eliminating patients very unlikely to be home dialysis or transplant candidates. Multiple commenters recommended exclusions for socioeconomic status and suggested ICD-10 diagnostic codes as exclusion criteria (e.g., Z59.0 for homelessness). CMS notes that most of the suggested codes are underutilized and vulnerable to

gaming. Support was expressed for exclusion using age and functional status, which CMS rejected for absence of consensus criteria. Exclusion for cancer was supported by multiple commenters but CMS states that the suitability of cancer patients for home dialysis or transplantation is best considered on a case-by-case basis than automatic blanket exclusion. Most commenters agreed with exclusions from attribution of beneficiaries with dementia diagnoses and those electing hospice. Lists of diagnose that typically are contraindications to solid organ transplantation were suggested as attribution exclusions and CMS considers these when discussing risk adjustment later in the rule. Finally, numerous commenters voiced support for excluding beneficiaries residing in nursing facilities from attribution. CMS agrees and modifies the attribution exclusion criteria accordingly.

CMS finalizes using the claim service date of service when making attribution decisions. The proposed attribution exclusions are finalized with two clarifications: 1) a dementia diagnosis must be made during the given attribution month or the preceding 12 months according to the most recent dementia criteria and defined using the dementia-related codes from the Hierarchical Conditions Category (HCC) Risk Adjustment Model ICD-10-CM Mappings;[47] and 2) the beneficiary's age on the first day of an attribution month will be used when applying the exclusion for age under 18 years. CMS concludes by adding an exclusion from attribution for beneficiaries residing in or receiving dialysis in a SNF or nursing facility.

c. Attributed Services

(1) ESRD Facilities

CMS proposed that an attribution-eligible beneficiary would be attributed to an ESRD facility for any month in which the beneficiary received renal dialysis services (other than solely for AKI) and received the plurality of that month's dialysis treatments at that facility. Should the beneficiary receive an equal number of treatments from two or more facilities in a month, attribution would be made based on the earliest treatment date for that month.[48] CMS also proposed to identify claims for facility attribution as those with Type of Bill 072X; where the type of facility code is 7 and the type of care code is 2, and that have a claim through date during the month for attribution. Finally, CMS proposed that pre-emptive transplant beneficiaries would not be attributed to facilities since they did not receive dialysis treatments and thereby had no care relationships with facilities.

CMS received a recommendation that a beneficiary not be attributed to a facility during a month when the beneficiary also received 3 or more treatments in another facility, and that attribution should be made based upon the site of the most treatments. CMS believes that the proposed plurality approach best reflects the facility with primary responsibility for providing dialysis services to a beneficiary during a month.

[47] The 2020 Midyear Final ICD-10-CM Mappings are available at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/Risk2020.
[48] If the earliest claim date is the same for both facilities, CMS makes a random attribution to one of the 2 facilities.

CMS finalizes their proposals for beneficiary attribution to ESRD facilities as proposed with clarifications: the date of service will replace the claim through date, attribution to a facility that is not an ETC Model participant is possible and permissible, and the regulation text of §512.360 will be updated where applicable with the finalized "pre-emptive living donor transplant (LDT) beneficiary" terminology.

(2) Managing Clinicians

CMS proposed to identify claims for attribution to a Managing Clinician using CPT codes 90957 through 90962 plus 90965 through 90966. Attribution must be handled differently for pre-emptive transplant beneficiaries who are not yet dialyzed and to whom the MCP does not apply. As described earlier (section IV.C.6(c)(1) of this summary), CMS proposed attribution for these beneficiaries based on volume of services provided during the months between the start of the MY and the month of the transplant. Attribution for those months would be made to the clinician furnishing the highest number of services to the beneficiary.

Commenters suggested alternative approaches for pre-emptive transplant beneficiary attribution, such as the Managing Clinician who referred the beneficiary to the transplant center. CMS continues to regard the highest service volume clinician as the one with the greatest share of responsibility for the beneficiary's care, having shepherded the patient and family through the living donor transplant process.

CMS finalizes their proposals for attribution to Managing Clinicians as proposed with minor modifications: using the date of service rather than the claims through date, adopting the revised living donor transplant terminology, and using the earliest attributed service date as a tiebreaker if needed.

d. Performance Assessment (§512.365)

CMS proposed 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). Commenters were supportive of this approach to performance measurement. CMS finalizes their proposal, modified only to use the newly finalized term Pre-emptive Living Donor Transplant (LDT) Beneficiary, consistent with the inclusion of that specific patient population in the revised transplant rate calculation (see below).

(1) Home Dialysis Rate

CMS proposed to define the home dialysis rate as the rate of ESRD beneficiaries attributed to an ETC Model participant who dialyzed at home during the relevant measurement year (MY). CMS further proposed that beneficiary years for both the clinician and facility home dialysis rates 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.

Commenters suggested adding a shared decision-making measure(s) to the rate calculation; adding ESRD beneficiaries enrolled in Medicare Advantage plans to the rate's numerator, since they often utilize in-center self-dialysis; and excluding patients residing and dialyzing in SNFs or nursing facilities, a situation more akin to in-center than home dialysis. CMS responds that a shared decision-making measure would be vulnerable to gaming and that there is no available measure specific for home dialysis. CMS notes that beneficiaries enrolled in MA are excluded from ETC Model attribution and those from SNFs and nursing facilities have just been added to the exclusion list. CMS finalizes the home dialysis rate definition and general provisions as proposed.

(a) ESRD Facility Home Dialysis Rate

The proposed formula for the facility home dialysis rate is shown below and utilizes treatment years for beneficiaries attributed to the facility as described above. Treatment months would be identified by Type of Bill 072X for the denominator and by Type of Bill 072X, with condition codes 74, 75, 76, or 80. CMS considered but decided against proposing to include beneficiaries performing self-dialysis or temporary peritoneal dialysis (PD) in a facility because they lack clear consensus definitions and are billed using in-center codes.

Many commenters supported adding self-dialyzing beneficiaries to the rate's numerator, pointing out 1) that condition 72 allows tracking of self-dialysis; and 2) citing the definition of self-dialysis at 42 CFR 494.10: dialysis performed with little or no professional assistance by an ESRD patient or caregiver who has completed an appropriate course of training (specified in §494.100(a)). CMS states that self-dialysis may support a gradual transition from in-center to home dialysis, and accepts that condition code 72 allows self-dialysis tracking, enabling addition of those beneficiaries to the home dialysis facility rate calculation. CMS, however, rejects suggestions for adding all beneficiaries who have received home-dialysis training or re-training (condition codes 73 and 87, respectively) or begin PD urgently (condition 71 with revenue code 0831) as unnecessary for properly testing the ETC Model.

CMS finalizes the proposed home dialysis rate for facilities with modifications:

- To include claims with condition code 72 for self-dialysis and include one-half of the resulting treatment beneficiary years to the rate's numerator;
- Not to include claims with condition code 75 (no longer a valid code) and code 80 (SNF and nursing facility "home" dialysis) and retaining condition codes 74 and 76;
- Remove references to risk adjustment methodology (not being finalized); and
- Change references to reliability adjustment to references to aggregation.

Facility home dialysis rate, proposed =
Home dialysis treatment beneficiary years / Total dialysis treatment beneficiary years

Facility home dialysis rate, final =
*Home dialysis treatment beneficiary years + 0.5 * Self-dialysis treatment beneficiary years / Total dialysis treatment beneficiary years*

(b) Managing Clinician Home Dialysis Rate

The proposed formula for the Managing Clinician home dialysis rate is shown below and uses treatment years for beneficiaries attributed to the Managing Clinician as described above. Treatment months for the denominator would be identified by claims for professional services with CPT codes 90957 through 90962 and 90965-90966 (in-center dialysis) and for the numerator would be 90965-90966 (home dialysis). Many commenters supported adding self-dialyzing beneficiaries to the rate's numerator and CMS provides a discussion analogous to that given for adding this group of beneficiaries to the facility home dialysis rate. CMS reaches a similar conclusion, adding one-half of the self-dialysis treatment years to the Managing Clinician home dialysis rate numerator. Self-dialysis claims would be identified as is done for the facility rate (type of bill 072X with condition code 72) as there are no CPT codes for self-dialysis MCP services.

CMS finalizes the proposed home dialysis rate for Managing Clinicians with modifications:

- To include claims with condition code 72 for self-dialysis and include one-half of the resulting treatment beneficiary years to the rate's numerator;
- Remove references to risk adjustment methodology (not being finalized); and
- Change references to reliability adjustment to references to aggregation.

Clinician home dialysis rate, proposed =
Home dialysis treatment beneficiary years / Total dialysis treatment beneficiary years

Clinician home dialysis rate, final =
*Home dialysis treatment beneficiary years + 0.5 * Self-dialysis treatment beneficiary years / Total dialysis treatment beneficiary years*

(2) Transplant Rate

CMS proposed that the transplant rate would include beneficiaries receiving deceased donor and living related kidney transplants during a single Measurement Year (MY). Beneficiaries 75 years or older or who were in a SNF at any point during a month were proposed for exclusion from transplant rates, as these beneficiaries are unlikely to be transplant candidates. Beneficiaries electing hospice would also be excluded as they are not eligible for facility or managing clinician attribution under the ETC Model. CMS reviews having considered using rates of transplant waitlisting rather than actual transplant rates but did not do so because the most relevant outcome of the ETC Model is in fact kidney transplantation, not waitlisting, and transplant waitlists do not capture living donor procedures. CMS also considered a multi-year period for the transplant rate to enhance statistical power since transplants are low-frequency events but concluded that reliability aggregation (a later step in MPS and PPA calculation) would restore statistical power when a single MY transplant rate was used.

Most commenters opposed using actual transplant rates given the limited influence of ETC participants on the transplant process, particularly for deceased donor transplants. Use of the Percentage of Prevalent Patients Waitlisted and Standardized First Kidney Transplant Waitlist Raito for Incident Dialysis Patients (SWR) measures was suggested. CMS notes that efforts within and outside of the ETC Model to increase organ donation are underway but desired effects will not be rapidly achieved. CMS, therefore, agrees with commenters that transplant waitlisting rate is a fairer performance assessment for ETC participants than actual transplant rate until organ donor shortages are resolved. CMS prefers the PPPW as the SWR does not measure pre-emptive transplants. Commenters also recommended exclusion for groups of beneficiaries ineligible for transplants. In response, CMS reviews the ETC Model attribution exclusions and the proposed transplant rate exclusions, finding them sufficient to capture most ineligible beneficiaries. CMS ends their discussion by noting that transplant organ longevity considerations primarily apply to deceased donor organs and acknowledges that a transplantation bonus is separately paid under the Innovation Center's voluntary Kidney Care Choices model.

CMS finalizes their proposals regarding transplant rates with modifications. The proposed transplant rate used for PPA-related calculations will be changed to the sum of the living donor transplant (LDT) rate and the transplant waitlist rate. CMS creates a transplant waitlist rate that builds on the PPPW measure but incorporates the ETC Model attribution methodology. CMS clarifies that beneficiaries with transplants who return to maintenance dialysis will be added into the denominators of the transplant waitlist rate and living donor transplant rate. The finalized facility and managing clinician transplant rates are shown below. CMS removes references to risk adjustment methodology and changes references to reliability adjustment to aggregation.

Kidney waitlist data are obtained from the Scientific Registry of Transplant Surgeons (SRTR). Transplant data are taken from SRTR and Medicare data (DRGs and ICD-10-PCS codes).

Facility transplant rate = Facility transplant waitlist rate (TWR) + Facility LDT transplant rate

Facility TWR = Total attributed beneficiary years on waitlist /
Total dialysis treatment attributed beneficiary years during the MY

Facility LDT = Total attributed LDT beneficiary years during the MY /
Total dialysis treatment attributed beneficiary years during the MY

Clinician transplant rate = Clinician transplant waitlist rate (TWR) + Clinician LDT transplant rate

Clinician TWR = Total attributed beneficiary years on waitlist /
Total dialysis treatment attributed beneficiary years during the MY

Clinician LDT = (Total attributed LDT beneficiary years during the MY +
Total number Pre-emptive LDT beneficiary years during the MY) /
(Total dialysis treatment attributed beneficiary years during the MY +
Total pre-emptive attributed LDT beneficiary years during the MY

(3) Risk Adjustment

(a) Home Dialysis Rate

CMS proposed to use the CMS-HCC (Hierarchical Condition Category) ESRD Dialysis Model to risk adjust the home dialysis rates for both clinicians and facilities, based on the most recent final risk score available for the beneficiary at the time of rate calculation. CMS notes that internal analyses had shown home dialysis beneficiaries had lower risk scores than those dialyzed in-center. CMS also considered not applying any risk adjustment methodology as none available account for the housing insecurity that significantly influences home dialysis utilization, but rejected this alternative as likely to disproportionately disadvantage ETC Model participants caring for sicker beneficiaries. CMS also decided against creating an ETC Model-specific methodology.

Most commenters opposed use of the HCC ESRD Dialysis Model for ETC home dialysis rate risk adjustment for reasons including that the HCC model is designed to project MA spending rather than risk adjust performance measures, overall health status is not the strongest predictor of home dialysis uptake, and the correlation found during analysis by CMS was not causative. CMS responds by describing a subsequent additional analysis relating HCC scores to home dialysis rates; while a statistically significant correlation remained, its explanatory power for predicting home dialysis use was very low (1.5 percent).

CMS, therefore, does not finalize the proposed risk adjustment using the CMS-HCC score and instead finalizes the home dialysis rate calculations without risk adjustment, having found no satisfactory and available methodology. Other commenters suggested various socioeconomic status variables including adapting the methodology of the Hospital Readmission Reduction Program. CMS prefers to defer risk adjustment entirely at this time rather than base it solely on socioeconomic factors,

(b) Transplant Rate

CMS proposed to risk adjust transplant rates using methodology taken from the PPPW measure, which is based on age brackets (e.g., 15-55, 56-70 years). Determinations would use beneficiary age on the last day of each MY month. Facility and clinician transplant rates would be adjusted to account for their respective relative distributions of attributed beneficiaries across age brackets compared to the national distribution of beneficiaries not excluded from distribution. CMS considered using the SWR for risk adjustment purposes but found its narrow focus on the first post-transplant year less well suited to the ETC Model than the PPPW.

Some commenters criticized use of the PPPW methodology alone, advocating consideration of other factors such as contraindications to transplantation. CMS disagrees, particularly since the transplant rate is being modified to include only living donor transplants. CMS finalizes that the transplant waitlist portion of the revised transplant rate will be risk adjusted based on beneficiary age categories (adapted from the PPPW), taking into account the relative percentage of the model participant's attributed beneficiaries in each age category relative to the national age

distribution of beneficiaries not excluded from attribution. CMS concludes by finalizing that the living donor portion of the revised transplant rate will not be risk adjusted due to small sample sizes.

(4) Reliability Adjustments and Aggregation

CMS proposed applying reliability adjustments separately to each ETC Model participant's home dialysis and transplant rates due to concerns about accuracy and precision of rates calculated with repeated measures of small, overlapping sample sizes. CMS states that the adjustment would create a weighted average between an individual participant's rate and that participant's aggregation group for use in subsequent PPA-related calculations based upon calculated reliability factors for each participant. (The statistical modeling by which reliability values would be determined is not described in the proposed rule or this final rule.) After identifying practitioners by NPIs, group practitioners by TINs, and facilities by their locations as listed in PECOS, CMS proposed to place them in aggregation groups as follows:

- Solo practitioners (NPI) are aggregated with all managing clinicians in their HRR.
- Group practice members (NPI) are combined under their TINs and TINs are aggregated with all managing clinicians in their HRR.
- Each ESRD subsidiary facility (owned in whole or part by another entity) would be combined into an aggregation group with all other subsidiary facilities of its parent entity in its HRR.
- A facility that is not a subsidiary facility would be combined into an aggregation group with all other individually-owned facilities in its HRR.

Commenters observed that the reliability adjustment lacked transparency and was difficult to grasp based on the information provided in the proposed rule. In response, CMS plans not to finalize the reliability adjustment, considering it unnecessary due to other changes that are being finalized for the aggregation methodology and participant low-volume thresholds. Objections also were voiced to the proposed aggregation rules shown above, such as accounting for the effect of the presence of centralized facilities focusing solely on home dialysis services. CMS declines to consider aggregation of virtual groups and describes a modified aggregation rules set as follows:

- Solo practitioner performance is assessed solely at the individual NPI level (no further aggregation).
- Group practice members (NPI) are aggregated to their TIN and performance is assessed solely at the TIN level (no further aggregation).
- Each ESRD subsidiary facility (owned in whole or part by another entity) would be combined into an aggregation group with all other subsidiary facilities of its parent entity in its HRR; performance would be assessed solely at the aggregated group level.
- Performance assessment for a facility that is not a subsidiary facility would be conducted solely at the individual facility level (no further aggregation).

CMS takes the following final actions: 1) removing the reliability adjustment for all ETC Model participants; 2) adopting the modified aggregation rules set (as listed above); and 3) CMS will identify subsidiary facilities through their Chain TIN and Chain Name listed in PECOS and will use other CMS data sources to identify and correct mismatches (e.g., CrownWEB)

e. Benchmarking and MPS Scoring (§512.370)

(1) Achievement score

For achievement scoring, CMS proposed to compare ETC Model participants' home dialysis and transplant rates for MYs 1 and 2 against national benchmarks that would be derived using the corresponding rates calculated for the nonparticipant facilities and clinicians of the comparison geographic group HRRs. Initial benchmarks would be derived from historical data from the comparison areas for the "Benchmark Year", a 12-month data period that would begin 18 months before the start of a MY and end 6 months before the start of that MY. Benchmark construction would utilize methodology identical to that used for calculating the home dialysis and transplant rates for ETC Model participants. CMS acknowledges that rates of home dialysis, transplant waitlisting, and living donor transplants are likely to change over time and states their intent to reflect those changes by increasing model participants' benchmarks for future MYs. CMS mentions a potential goal that the maximum achievement score for MYs 9 and 10 could require a combined home dialysis and transplant rate of 80 percent.

Some commenters opposed the achievement benchmarks as proposed. Criticisms included that 1) the methodology merely demonstrates comparative performance among participants rather than real, absolute kidney care achievements; 2) large dialysis organizations with participants in both the selected (model test) HRRs and the comparison (benchmark) HRRs will be able to game the measurements by varying their support for home dialysis at comparison facilities; and 3) there is poor performance differentiation among participants at the lower scoring levels. Numerous commenters voiced concern about the lack of transparency and the uncertainty related to CMS' incomplete plan for future benchmarking methodology changes, particularly given the described goal that the MY10 maximum achievement score would equate to 80 percent of beneficiaries receiving transplants or dialyzing at home. Others suggested adoption of alternative methodologies (e.g., from the ESRD QIP or the CEC model), setting benchmarks regionally rather than nationally; and adjusting benchmarks to reflect socioeconomic factors.

CMS expresses continued support for the proposed achievement scoring methodology and emphasizes that future benchmark modifications will only be undertaken through notice-and-comment rulemaking. CMS cites the finalized aggregation methodology as a deterrent to gaming through market share. CMS emphasizes the aspirational nature of the MY10 goal of a combined 80 percent home dialysis and transplant rate. CMS notes that the proposed ETC benchmarking and scoring methodology is the same as that used for scoring CEC Model quality performance. CMS commits to continued use of the finalized MYs 1 and 2 benchmarking methodology for future MYs if rulemaking for potential benchmark changes cannot be completed with sufficient notice to participants in advance of the future MYs. CMS also

commits to ongoing monitoring to identify potential unintended consequences of the achievement score methodology.

Some commenters expressed particular concern about earning achievement points based on transplant rates given the low frequency of transplantation and the many factors in the transplant process that are outside of ETC Model participants' control. CMS responds that the revised finalized transplant rate should mitigate this concern since the rate no longer includes deceased donor cases.

(2) Improvement Score

CMS proposed to calculate improvement scores for all MYs, comparing model participant performance to benchmarks created using their own historical performances on home dialysis and transplant rates. CMS proposed that a model participant could not reach the highest scoring level solely through improvement score points. Commenters were supportive of the proposed improvement score methodology (self-comparison) but several opposed limiting participants' abilities to reach the highest performance score based solely on improvement points. CMS disagrees, noting that limitation on improvement points is consistent with other CMS programs. CMS notes that a negative PPA can be avoided based solely on improvement points.

(3) Modality Performance Score

Achievement and improvement score points are awarded to ETC Model participants related to home dialysis rates and transplant rates. For each participant, the achievement and/or improvement points are added to produce a Modality Performance Score (MPS). The MPS formula as proposed is shown below. CMS notes that the higher relative weight of the home dialysis rate in the MPS was chosen to reflect the added challenge that the low frequency of transplants performed presents to earning transplant score points. The MPS is used to determine the participant's PPA (described below).

$$\begin{aligned} Modality\ Performance\ Score\ (MPS) = \ & 2 \times (Higher\ of\ home\ dialysis\ rate \\ & achievement\ or\ improvement\ score) \\ & + \ (Higher\ of\ transplant\ rate \\ & achievement\ or\ improvement\ score) \end{aligned}$$

Concern was voiced that the higher relative contribution of the home dialysis rate to a participant's MPS could function to penalize small ESRD facilitates unable to develop or maintain home dialysis programs or lead to pressuring of beneficiaries by model participants to switch to home dialysis. CMS expresses continued belief that increasing transplant rates presents more challenges than increasing home dialysis rates and retains the MPS formula unchanged.

CMS takes the following final actions regarding benchmarking and scoring:

- Adopts continued use of the finalized MY1 and MY2 benchmarking methodology for future MYs if rulemaking for potential benchmark updates cannot be completed with sufficient advance notice to participants before the beginning of future MYs; and
- Finalizes the definition of Benchmark Year as proposed.

The finalized scoring methodology for assessment of MY1 and MY2 achievement and improvement scores on the home dialysis and transplant rates is detailed in the table below.

TABLE S-1: FINAL SCORING METHODOLOGY FOR ASSESSMENT OF MEASUREMENT YEARS 1 AND 2 ACHIEVEMENT 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 comparison geographic areas during the benchmark year	0	Less than or equal to benchmark year rate

*Table created by HPA for this summary by adaptation from Table 13 of the proposed rule (84 FR 34557) using the regulation text at §512.370(b) and (c) MY Measurement Year

f. Performance Payment Adjustment (PPA)

CMS reprises that as proposed the PPA would make upward and downward changes to payments to ETC Model participants for dialysis and dialysis-related services; PPA magnitude would increase over time. CMS states that the PPA magnitude was designed to be comparable to the adjustments of the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program under the Medicare Physician Fee Schedule, without overly harming ETC participants through reduced payments. The PPA was designed to be asymmetrical – downside risk exceeds upside reward – to provide what CMS regards as a robust incentive and to be greater for facilities than for clinicians, as the former are viewed by CMS as better able to bear downside risk. CMS

also proposed to apply the PPA such that beneficiary cost sharing is not increased, and to all claims regardless of whether Medicare is the primary or secondary payer. (A stepwise outline of the calculation processes for the Facility and Clinician PPAs is provided at the end of this section.)

CMS received many comments about their PPA proposals, the great majority of which opposed one or more provisions. Key points made by commenters include:

- The PPA should be upside only.
- The onset of downside PPA application should be delayed.
- The magnitude of the downside PPA percentage should be reduced.
- The Facility PPA should not apply to home dialysis services.
- The design and structure of the PPA should mimic that of the ESRD QIP.
- The PPA should be adjusted to allow the ETC Model to become an Advanced APM or ETC Model clinicians should be made MIPS-exempt.
- The PPA could have unintended consequences including closure of small, independent, and rural ESRD facilities; destabilization of the Medicare ESRD benefit, and application of undue pressure on beneficiaries to elect home dialysis.

CMS responses emphasize the following:

- The PPA's design appropriately encourages all dialysis facilities to provide home dialysis services, increasing home dialysis availability to the full range of ESRD beneficiaries.
- The downside risk component of the PPA is essential to accomplishing the model's goals.
- PPA downside risk is designed to be robust but not overly harmful and to parallel the risk percentages of the MIPS track for 2020 and future years.
- The PPA will not impact payment until the first PPA period begins on July 1, 2022.
- The combined timeline of the upside-only HDPA and the two-sided PPA was purposefully designed to provide a smooth and gradual transition from process-based incentive to outcomes-based incentive.
- The PPA's structure as a percentage and the model's low-volume threshold provision protect smaller facilities from excess harm.
- The proposed magnitude of the facility and clinician PPA percentages were set higher than needed to achieve the ETC Model's goals.
- Changing the PPA to allow the ETC Model to qualify as an Advanced APM would require increasing the PPA downside risk in the early years of the model.
- Long-term benefits of changes induced by the model and its embedded PPA will be improved quality of care for ESRD beneficiaries and cost savings to the Medicare program, meeting the goals of Innovation Center-sponsored initiatives.
- ETC Model participating facilities may also elect to participate in the KCC model that offers incentives separate and different from those of the ETC Model but also higher downside risk.

CMS finalizes the general provisions of the PPA as proposed with modifications. Final actions include:

- Modifying the schedule for applying the PPA to reflect the January 1, 2021 model start date, and
- Reducing the magnitude of the maximum PPA amounts for each PPA Period by 2 percent. (While the reduction is stated as 2 percent, the reductions in Tables 14.a and 15.a appear to range from 0.5 to 3.0 percent.)

(1) Facility PPA

CMS highlights proposals specific to the facility PPA, including 1) the adjustment is applied to the Adjusted ESRD PPS Per Treatment Base Rate; 2) beneficiary cost sharing would be based on the amount that would have been paid under the ESRD PPS (i.e., would not increase); 3) claims subject to payment adjustment would be identified by Type of Bill 072X with facility code 7 and type of care 2 for beneficiaries age 18 and older; and 4) the adjustment amounts and PPA period schedule were provided as Table 14 of the proposed rule (84 FR 34558). CMS notes that the CY 2020 ESRD PPS final rule established the TPNIES add-on payment to the ESRD PPS Per Treatment Amount; the PPA would apply to the Adjusted Per Treatment Base Rate and therefore not be applied to the TPNIES.

Commenters recommended that claims with condition code 73 (home dialysis training) be subject to the PPA. CMS declines, stating that the PPA is designed to incentive home dialysis rather than training for home dialysis *per se*.

CMS finalizes the Facility PPA as proposed with modifications:

- Adjust the beneficiary age qualification language to include those age 18 or older before the first day of the month for ease of CMS claims processing;
- Use the claim date of service rather than claim through date in identifying claims subject to the PPA for ease of CMS claims processing;
- Not to apply the PPA to the TPNIES; and
- Reduce the magnitude of the maximum PPA amounts by 2 percent. (While the reduction is stated as 2 percent, the reductions in Tables 14.a and 15.a appear to range from 0.5 to 3.0 percent.)

The formula for the final ESRD PPS per treatment amount and the final Facility PPA payment amounts and schedule are provided below (reproduced from the rule).

$$Final\ ESRD\ PPS\ Per\ Treatment\ Payment\ Amount\ with\ PPA\ and\ HDPA = ((Adjusted\ ESRD\ PPS\ per\ Treatment\ Base\ Rate * (Facility\ HDPA + Facility\ PPA)) + Training\ Add\ On + TDAPA + TPNIES) * ESRD\ QIP\ Factor + Outlier\ Payment * ESRD\ QIP\ Factor$$

TABLE 14.a: FACILITY PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

	MPS[b]	PPA Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility PPA[a]	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.5%	-5.0%
	≤ .5	-5.0%	-6.0%	-7.0%	-9.0%	-10.0%

[a] PPA Performance Payment Adjustment
[b] MPS Modality Performance Score

(2) Clinician PPA

CMS highlights proposals specific to the clinician PPA, including 1) the adjustment is applied to the amount otherwise paid under Part B to avoid increasing beneficiary cost sharing; 2) professional claims subject to payment adjustment would be identified by CPT codes 90957-90962 and 90965-90966 (MCP services) for beneficiaries age 18 and older; and 3) the adjustment amounts and PPA period schedule were provided as Table 15 of the proposed rule (84 FR 34559).

The only comment noted by CMS specific to the clinician PPA expressed support for application of the PPA when Medicare is the secondary payer.

CMS finalizes the Clinician PPA as proposed with modifications:

- Adjust the beneficiary age qualification language to include those age 18 or older before the first day of the moth, for ease of CMS claims processing;
- Use the claim date of service rather than claim through date in identifying claims subject to the PPA, for ease of CMS claims processing; and
- Reduce the magnitude of the maximum PPA amounts by 2 percent. (While the reduction is stated as 2 percent, the reductions in Tables 14.a and 15.a appear to range from 0.5 to 3.0 percent.)

The final Clinician PPA payment amounts and schedule are provided below.

TABLE 15.a: CLINICIAN PERFORMANCE PAYMENT ADJUSTMENT AMOUNTS AND SCHEDULE

	MPS[b]	PPA Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
Facility PPA[a]	≤ 6	+4.0%	+5.0%	+6.0%	+7.0%	+8.0%
	≤ 5	+2.0%	+2.5%	+3.0%	+3.5%	+4.0%
	≤ 3.5	0%	0%	0%	0%	0%
	≤ 2	-2.5%	-3.0%	-3.5%	-4.0%	-4.5%

	MPS[b]	PPA Period				
		1 and 2	3 and 4	5 and 6	7 and 8	9 and 10
	≤ .5	-5.0%	-6.0%	-7.0%	-8.0%	-9.0%

[a] PPA Performance Payment Adjustment
[b] MPS Modality Performance Score

Outline of PPA calculation processes

Facility

1. Assess the home dialysis and transplant rates using the formulas based upon beneficiary dialysis treatment years, as provided in summary section IV.B.6.d(1) and (2) above.

2. Risk adjust the rates.

   a. There is no risk adjustment for the facility home dialysis rate.

   b. For the transplantation rate, use beneficiary age and PPPW as described in summary section IV.B.6.d(3)(b) above.

3. Apply the revised aggregation rules set from summary section IV.B.6.d(4) above. 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 summary section IV.B.6.e and shown in Table S-1.

5. Calculate the Modality Performance Score (MPS) for the facility as described in summary section IV.B.6.e above. Find the applicable MY and PPA adjustment period from Table 12.a.

6. Find the facility PPA amount from Table 14.a 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 summary section IV.B.6.d(1) and (2) above.

2. Risk adjust the rates.

   a. For the home dialysis rate, there is no risk adjustment.

   b. For the transplantation rate, use beneficiary age and PPPW as described in summary section IV.B.6.d(3)(b) above.

3. Apply the revised aggregation rules set from summary section IV.B.6.d(4) above.

4. Calculate achievement and improvement scores for the clinician for each rate as discussed in summary section IV.B.6.e and shown in Table S-1 above.

5. Calculate the Modality Performance Score (MPS) for the clinician as described in summary section IV.B.6.e. Find the applicable MY and PPA adjustment period from Table 12.a.

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

g. Low-Volume Threshold Exclusions for the PPA

(1) ESRD Facility

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 Model.

Many commenters supported establishing a low-volume threshold policy for ETC Model participant facilities but most also opposed the proposed threshold definition and recommended modifications. Opponents stated that the proposed definition would not properly identify the facilities at most risk due to their small volumes or rural locations, would stimulate further market consolidation, and would harm beneficiaries through facility closures. Suggested modifications included excluding a facility that is farther than 20 miles from the next nearest facility or is owned by an organization with $\leq$ 35 facilities; allowing small and low-volume facilities to aggregate into a virtual group; and using the ESRD PPS low-volume definition. Other recommendations included variations of reducing or eliminating downside PPA risk for low-volume facilities.

CMS responds that the proposed threshold was designed to balance appropriate protection of small, low-volume facilities with maintaining sufficient statistical reliability of the ETC Model to yield significant and generalizable results. CMS states that the suggested alternative thresholds are not suitable for operational reasons or inability to be adapted to the ETC Model's framework. CMS rejects the recommended adjustments to the PPA for low-volume facilities, for reasons similar to rejecting suggestions for change to the PPA in general (as discussed previously). Because of the finalized changes to the model's aggregation rules (see section IV.C.5.c(4) of the rule and section IV.C.6.d(4) of this summary), CMS states that more facilities will be excluded from PPA adjustments, especially those that are small and/or independent while preserving the statistical reliability of the model.

(2) Managing Clinicians

CMS proposed to set a low-volume threshold for application of the clinician PPA, as they may serve niche populations (e.g., rare childhood diseases) for whom statistically reliable home dialysis and transplantation rates could not be produced. CMS proposed setting the 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 expressing the threshold in total dollar value of Medicare claims paid but rejected this alternative due to wide variation in

services (and their associated payment rates) furnished by these clinicians. CMS received few comments, of which one recommended an opt-in option for clinicians meeting the exclusion threshold. CMS declines to do so to avoid jeopardizing the statistical reliability of home dialysis and transplantation rates used in PPA determinations for Managing Clinicians.

After publishing the proposed rule, CMS determined that the proposed policy lacked the desired statistical precision. Therefore, in this rule, CMS finalizes a modified low-volume threshold: Managing Clinicians in an aggregation group with fewer than 11 attributed ESRD beneficiary-years during an MY will be excluded from the PPA adjustment during the applicable PPA period. Because of the finalized changes to the model's aggregation rules (see section IV.C.5.c(4) of the rule and section IV.C.6.d(4) of this summary), CMS states that the modified low-volume threshold will exclude more clinicians from PPA adjustments than the proposed threshold but still support statistical reliability of the model.

h. Notification (§512.390(a)) (

During the first 6 months after a MY ends CMS would calculate and validate the MPS and associated PPA for each ETC Model participant. CMS proposed 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). Concern was voiced by a commenter that a single notification per year would not provide timely, actionable information to clinicians. CMS responds that clinicians would receive a notification prior to each PPA period, or two notifications per year. CMS finalizes the clinician notification provision as proposed.

i. Targeted Review (§512.390(b))

CMS proposed 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: home dialysis rate and transplant rate methodology; achievement and improvement benchmarking methodology; and MPS calculation methodology. Proposed elements of the review process would include:

- Written request for a targeted review submitted to CMS within 60 days of receiving an MPS result;
- Determination by CMS whether review is warranted within 60 days of the request;
- Submission by the participant of any supplemental information requested by CMS within 30 days;
- When an error is found, notification of the participant within 30 days thereafter;
- Resolution of any associated PPA payment discrepancy during the next PPA period; and
- Exemption of targeted review decision from appeal.

The sole commenter recommended that the period for requesting a targeted review be extended to 90 days and may be requested at a later date as specified by CMS, and changing the time for resolution of a payment discrepancy from the next PPA period to a time determined by CMS. CMS agrees and finalizes their proposed policy with modification that the participant request for

targeted review must be submitted within 90 days or at a later date as specified by CMS. Finally, CMS also clarifies that CMS must resolve any payment discrepancy in a time and manner determined by CMS.

7. Overlap with Other Innovation Center Models and CMS Programs

CMS proposed to treat potential overlaps with other Innovation Center models and CMS programs as follows:

- Apply HDPA and PPA for facilities 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;
- Apply HDPA and PPA for clinicians to the amount otherwise paid under Part B but prior to application of the MIPS payment adjustment factors;
- Allow selection of ETC participants from HRRs in which CEC ESCOs are active;
- Count ETC Model payment adjustments as expenditures under the Shared Savings Program and other CMS total-cost-of-care-initiatives; and
- Allow ETC participants to join entities formed under the Kidney Care Choices (KCC) voluntary model options.

Commenters urged that CMS test improving home dialysis and transplantation rates only through voluntary models; exclude beneficiaries already aligned to coordinated care model participants (e.g., CEC and KCC); exclude ETC Model payment adjustments from Shared Savings Program expenditures and other Innovation Center models; add quality measures for home dialysis and kidney transplants to the ESRD QIP in lieu of testing the ETC Model; and apply MIPS adjustment factors but not ETC Model adjustments to payments to Managing Clinicians who are ETC participants and also subject to MIPS. CMS declines to adopt any of the commenters' recommendations, citing the distinctly different goals and hypotheses being tested through the ETC and KCC models; preservation of the ability to reliably evaluate both the ETC and KCC model results; avoiding compromise of CMS' total cost-of-care models; and the different focus areas of the ETC Model and the MIPS program.

CMS additionally notes that although the CEC model has been extended through March 31, 2021 in response to the COVID-19 PHE, the overlap of the CEC and ETC Models will remain minimal (4 months) and that CEC ESCOs are equally likely to be located in ETC Selected and Comparison HRRs. CMS concludes by finalizing the provisions addressing model overlaps as proposed.

8. Medicare Program Waivers (§512.397)

CMS proposed to waive requirements (sections 1833(a), 1833(b), 1848(a)(1), 1881(b), and 1881(h)(1)(A) of the Act) to the extent necessary to make the ETC Model's payment adjustments described in this rule and not to change standard beneficiary cost sharing provisions. To test the

impact of broadening the KDE benefit on beneficiary renal replacement modality choices, CMS also proposed to waive requirements as follows:

- That only doctors, physician assistants, nurse practitioners, and clinical nurse specialists can furnish KDE services, allowing services to be provided by clinical staff under the direction of and incident to services of a Managing Clinician who is an ETC Participant;
- That the KDE benefit is covered only for Stage 4 CKD patients, permitting KDE for beneficiaries diagnosed with CKD Stage 5 or within 6 months of first ESRD diagnosis;
- That KDE session content include the management of co-morbidities and delaying the need for dialysis, when services are furnished to CKD Stage V beneficiaries or unless such content is relevant for the beneficiary; and
- That an outcomes assessment measuring beneficiary knowledge about CKD treatment options be performed by a qualified clinician during a KDE session, provided that the assessment is performed within one month of the final KDE session.

Most commenters were supportive and some requested multiple additional waivers that were not addressed in the proposed rule (e.g., allowing nurses to provide home dialysis visits via telehealth, increased payment for peritoneal dialysis catheter placement). CMS declines these requests, and notes that telehealth waivers are not necessary for ETC Model testing. CMS voices concern that beneficiary cost-sharing waivers could inadvertently induce beneficiaries to choose providers based on care cost rather than care quality. CMS finalizes the proposed waivers with minor modifications to enumerate the list of provider types allowed to provide KDE services; to permit KDE provision to beneficiaries within 6 months of dialysis initiation rather than ESRD diagnosis; and to clarify that the provider directing KDE services must be a Managing Clinician.

9. Compliance with Fraud and Abuse Laws

CMS did not propose any waivers of fraud and abuse provisions (e.g., section 1128A of the Act) for the ETC Model test. Participants must comply with all applicable laws and regulations. Waiver were requested by several commenters but CMS regards such waivers as unnecessary.

10. Beneficiary Protections (§512.330)

CMS proposed beneficiary protections beyond those discussed previously in the rule, including:

- Prohibiting ETC participants from influencing beneficiary choice of renal replacement modality by offering or paying remuneration that fails to comply with applicable laws;
- Stipulating full protection under Federal disability rights laws for disabled beneficiaries (including dementia and cognitive impairment) treated by ETC participants; and
- Notifying beneficiaries being treated by ETC participants of the provider or supplier's model participation through informational material to be displayed in office and facility locations where treatment is rendered;
    - CMS further proposed to provide a template with required content but allow participants to add their own original content.

Comments were received supporting various options for attributed beneficiaries to opt out of care under the model (e.g., formal opt-out attestation process, assistance for transferring care to clinicians or facilities not subject to model participation); to add a Beneficiary Ombudsman; and to require explicit disclosure of payment information by participants to beneficiaries. CMS disagrees with all of these comments finding them unnecessary or potentially harmful to generalizability of model test results.

CMS finalizes their beneficiary protection proposals with modifications: 1) to clarify that all regulations related to descriptive model materials and activities apply to the CMS-provided template beneficiary notification except for the required disclaimer (see section II.D.3 of the rule and section II.B.3 of this summary); and 2) to specify that the notification template will identify the clinician or facility as an ETC Model participant; provide instructions on how to contact the ESRD Network Organizations with any questions or concerns about model participation; and an affirmation of the ESRD beneficiary's protections under Medicare, including freedom to choose his or her provider or supplier and to select the treatment modality of his or her choice.

11. Monitoring

a. Monitoring Activities (§512.150)

CMS proposed monitoring activities beyond those discussed previously in the rule, including:

- Identifying unintended consequences by monitoring the utilization rates for home dialysis beneficiaries of back-up in-center dialysis and ESRD self-care retraining;
- Obtaining clinical data for home dialysis patients for events including fever, abnormal bleeding, access point problems, and significant weight and vital sign changes;
- Tracking home dialysis equipment and machine issues;
- Monitoring multiple data sources to compare complications for kidney transplant beneficiaries treated through the ETC Model with those treated in comparison areas; and
- Maximizing stakeholder engagement and input from beneficiaries, their representatives, and advocacy groups.

CMS received comments of support that included lengthy lists of additional events and conditions recommended for monitoring. CMS responds that some are already included in the proposed monitoring plan and that the others will help inform future plans. Concerns were voiced that the monitoring plan was too vague and would not rapidly identify issues, with which CMS disagrees, citing plan details and data sources other than claims. Support was expressed for reducing burden by merging the model's monitoring activities with an existing network or survey, but CMS states that separate monitoring is needed of the model's unique risk for inappropriate beneficiary steering to home dialysis. Specific accounting by peritoneal dialysis providers for complications of PD catheter insertion was recommended but CMS judged this request to be out-of-scope for this final rule. CMS concludes by finalizing their monitoring policy as proposed.

b. Quality Measures (§512.395)

CMS proposed to monitor quality of care delivered through the ETC Model by requiring facility reporting of two measures:

- 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.

Commenters supported using the proposed measures and without linking them to payment under the ETC Model. Commenters strongly recommended a measure of beneficiary experience and CMS agrees. CMS considers the In-Center Hemodialysis (ICH) CAHPS unsuitable as it fails to capture populations of major import to the model test, home dialysis and kidney transplant patients. CMS indicates an intent to develop a suitable experience measure that could be linked to ETC Model payments as early as the third year of the model. In response to suggestions for additional quality measures, CMS states that the two proposed are sufficient for monitoring care delivered through the model and notes that all model participants are subject to other CMS quality programs (e.g., ESRD QIP and MIPS). Substitution of mortality and hospitalization rates for the proposed ratios was recommended since the confidence intervals of the latter are wider. CMS disagrees and notes that the measures as ratios are NQF-endorsed and already reported publicly. A request to allow palliative dialysis as a patient-discretionary option excluded from the ESRD was judged out-of-scope for this final rule. CMS concludes by finalizing the quality measures for ETC Model monitoring as proposed.

12. Evaluation

CMS proposed that formal evaluation of the ETC Model would be conducted similarly to those for other Innovation Center models. 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 versus comparison areas. The evaluation would also explore qualitatively what changes were made by clinicians and facilities in response to the ETC Model, challenges faced, and lessons learned. CMS proposes a mixed- methods evaluation approach that includes qualitative and quantitative analyses, including a difference-in-differences approach or similar methodology. CMS proposed that the model's comparison group would be those HRRs not selected for mandatory model participation.

In response to commenters, CMS indicates expectations for annual reports and a summative report of the model testing results; confirms that potential negative impacts of the model would specifically be assessed; and states a belief that the model's research questions will appropriately address costs and patient and family experience at the end of life. CMS concludes by finalizing the proposed evaluation approach unchanged.

13. Learning System

CMS proposed to create and 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). CMS received supportive comments; one commenter recommended involving Medicare's Quality Improvement Organizations (QIOs) and changing the name from ETC Learning Collaborative to "Transplant First". CMS prefers to retain the original system name and does not support QIO involvement to allow the latter to pursue their other high priority work. Another suggestion was received to delay start of the transplantation component of the ETC Model until the ETC Learning Collaborative was well established but CMS believes such delay to be unnecessary. CMS finalizes their plan to proceed with learning system implementation.

14. Remedial Action (§§512.160(a) and (b))

CMS notes that remedial actions applicable to the ETC Model were outlined previously in this rule. CMS reports receiving no relevant comments and finalizes the grounds and options for such actions without modifications.

15. Termination of the ETC Model by CMS (§512.170)

CMS states that general provisions of this rule concerning model termination would be specifically applicable to the ETC Model (e.g., written notice to participants). Termination would be exempt from administrative or judicial review. Absent relevant comments, CMS finalizes their termination policy as proposed.

V. Regulatory Impact

A. Statement of Need

CMS discusses the reasons why the 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 will 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 will 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, 2021, with the final data submission ending in 2026.

CMS also discusses the need for the ESRD 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).[49] A regulatory impact analysis (RIA) must be prepared 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 RO Model and the ETC Model will be a net federal savings of $253 million over a 5–year performance period (2021 through 2025). Detailed estimates and assumptions are discussed below.

[49] 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 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)).

a. Radiation Oncology Model

CMS notes that the RO Model as finalized will include 30 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 500 PGPs (slightly over half, 275 of these, were freestanding radiation therapy centers) and 450 HOPDs furnishing RT services in those simulated selected CBSAs. The RO Model starting in January 2021 will have a 5-year performance period and include an estimated 348,000 episodes, 309,000 beneficiaries, and $5.3 billion in total episode spending of allowed charges (inclusive of beneficiary cost sharing).

Table 1 in the final rule (reproduced below) summarizes the estimated impact of the RO Model based on a January 1, 2021 start date. CMS estimates that on net the Medicare program will save $230 million over the 5 performance years (2021 through 2025). This is the net Medicare Part B impact that includes both Part B premium and MA rate financing interaction effects. The savings estimate is lower than the $260 million in the proposed rule due to changes to finalized policies including reduced discount factor, a smaller RO Model size of 30 percent of RO episodes in eligible geographic areas, a low-volume opt-out option, and a stop-loss policy for RO participants with fewer than 60 episodes during 2016-2018. CMS projects that 83 percent of physician participants (as measured by unique NPI) will receive the APM incentive payment under the Quality Payment Program at some point during the model performance period. The APM incentive payment applies only to the professional episode payment amounts and not the technical episode payment amounts. In addition, no APM incentive payments will be paid based on participation in the RO Model in 2021 and 2022, due to the two-year lag between the QP performance and payment periods. APM incentive payments are assumed to be made in 2023 and 2024.

Table 1. Estimates of Medicare Program Savings (Millions $) for Radiation Oncology Model (Starting January 1, 2021)

	Year of Model					
	2021	**2022**	**2023**	**2024**	**2025**	**Total***
Net Impact to Medicare Program Spending	-30	-40	-40	-50	-60	-230
Changes to Incurred FFS Spending	-30	-30	-40	-40	-50	-190
Changes to MA Capitation Payments	-20	-20	-30	-30	-40	-130
Part B Premium Revenue Offset	10	10	10	20	20	80
Total APM Incentive Payments	0	0	10	10	0	20
Episode Allowed Charges	990	1,030	1,060	1,100	1,120	5,300
Episode Medicare Payment	770	800	830	860	880	4,130
Total Number of Episodes	67,000	68,000	70,000	71,000	72,000	348,000
Total Number of Beneficiaries	65,000	67,000	68,000	69,000	70,000	309,000

*Negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase.
*Totals may not sum due to rounding and from beneficiaries that have cancer treatment spanning multiple years.

To calculate these numbers, CMS used a stochastic simulation to estimate the financial impacts of the RO Model relative to baseline assumptions. The model relied on data from retrospectively constructed RT episodes between 2016 and 2018. Among other assumptions, CMS assumed that traditional FFS payment system billing patterns continue and that net OPPS updates would outpace the PFS by 3.0 percent on average annually between 2019 and 2025. 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 1.0 percent annually for the bundled services absent the model, then Medicare spending to be approximately budget neutral, and conversely if the V&I growth increases by 1.0 percent annually, then net outlays would be reduced by $470 million. CMS also notes that these estimates assume that Medicare FFS billing and treatment patterns for beneficiaries observed during the 2016-2018 period resume by the start of 2021. This is uncertain, however, given the duration of the current COVID-19 pandemic and its severity.

b. ESRD Treatment Choices Model

The ETC Model will include about 30 percent (down from 50 percent from the proposed rule) 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. There are an estimated 7,196 ESRD facilities, 2,286 Managing Clinicians, 383,057 beneficiaries across 306 HRRs that meet the eligibility criteria for attribution to ETC participants under the Model.

Table 2 in the final rule (reproduced below) summarizes the estimated impact of the 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 will save a net total of $23 million between January 1, 2021 and June 30, 2017 ($32 million from the PPA and HDPA less $9 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 $57 million over this period compared with $1 million in savings from the Managing Clinician PPA. The decrease in estimated net savings from the proposed rule of $169 million largely stems from the reduction in the magnitude of the performance payment adjustments to ETC Model participating facilities. Smaller savings than shown in the proposed rule are also related to similar changes in clinician performance payment adjustments and other changes that impact the PPA determination (e.g., benchmarking methodology, low-volume clinician threshold).

Table 2. Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices Model

	Year of Model							
	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**6.5 Year Total***
Net Impact to Medicare Spending	13	7	0	-5	-10	-16	-8	**-23**

	Year of Model							
Overall PPA Net & HDPA	12	5	-2	-7	-12	-18	-10	**-32**
Clinician PPA Downward Adjustment		-1	-2	-3	-3	-4	-2	-15
Clinician PPA Upward Adjustment		1	2	3	3	4	2	14
Clinician PPA Net		0	0	0	0	0	0	-1
Clinician HDPA	1	1	1					3
Facility Downward Adjustment		-9	-20	-24	-33	-42	-23	-151
Facility Upward Adjustment		5	13	17	21	25	13	94
Facility PPA Net		-4	-7	-7	-12	-17	-9	-57
Facility HDPA	10	8	5					23
Total PPA Downward Adjustment		-10	-22	-27	-36	-46	-25	-166
Total PPA Upward Adjustment		6	15	20	24	28	15	108
Total PPA Net		-4	-8	-7	-12	-18	-10	-58
Total HDPA	12	9	5					26
KDE Benefit Costs	0	1	1	1	1	1	1	**3**
HD Training Costs	1	1	1	1	1	1	1	**6**

*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 rate averaging 3 percentage points per year. CMS notes that this 3-percentage point per year 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. Peritoneal dialysis rates are used as a proxy for home dialysis rates.

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 $117 million in losses, compared to a total of $23 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 will 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 will drop to 15 percent by the end of the

model testing period – about 2,360 additional transplants and an estimated $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.

Various analyses were performed to examine the potential impact of COVID-19 on the kidney transplant list and other factors, and based on these analyses CMS did not believe it needed to make any further adjustments to its assumptions.

2. Effects on Medicare Beneficiaries

CMS anticipates that on average the RO Model will modestly reduce the cost to beneficiaries receiving RT services. Beneficiaries will 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 (3.75 percent for PC and 4.75 percent for TC), the beneficiary cost-sharing, on average, will be reduced relative to what typically would be paid under traditional Medicare FFS for an episode of care. CMS notes that the current limit on beneficiary cost-sharing in the HOPD setting to the inpatient deductible will continue under the RO Model.

With respect to the ETC Model, CMS also anticipates that the model will have a negligible impact on the cost to beneficiaries receiving dialysis. Medicare beneficiaries are generally responsible for 20 percent of the allowed charge for services furnished by providers and suppliers. This policy will remain in effect under the ETC Model. CMS notes that beneficiaries will be held harmless from the application of the Clinician PPA and the Clinician HDPA, and beneficiaries will 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 the 950 expected participants to learn the billing system for the RO Model is $183.14 per participant, or approximately $174,000 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 anticipates that both models will likely include beneficiaries and providers completing surveys but does not estimate the burden. It states that the burden depends on the length, complexity, and frequency of the surveys.
- For quality measure and clinical data element reporting, CMS estimates reporting these elements for the RO Model to be about $1,743 per entity per year or a total of about $1.7

million for the estimated 950 RO Model participants. The ETC Model, however, does not require any additional quality measure or clinical data element reporting by ETC participants, and thus no additional burden.

- CMS anticipates the total burden estimate for reading and interpreting the RO Model rule at about $5 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 final 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 would be reduced by 6.0 percent to PGPs and 4.7 percent for HOPDs. CMS expects 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 complying with the quality measure and clinical data element reporting to be about $1,743 per entity per year. It estimates the administrative cost of reading and interpreting this final rule per small entity to be about $1,093 for reading and an additional $183 to learn the billing system.

For the ETC Model, CMS assumes that the great majority of Managing Clinicians will be small entities and that the greater majority of ESRD entities will not be small entities. CMS concludes that the low volume threshold exclusions, risk adjustments of the transplant rate, and other policies only affect payment for selected services and thus will not have an economically significant impact on a substantial number of small entities.

5. Other Effects

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

6. Accounting Statements

Tables 3 and 4 in the final rule show the classifications of transfers, benefits, and costs associated with the provisions of the final rule.

VI. APPENDIX

TABLE 2-LIST OF RO MODEL BUNDLED HCPCS CODES

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

HCPCS	HCPCS Description	Category
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
77333	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77334	Radiation treatment aid(s)	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77336	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77338	Design mlc device for imrt	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77370	Radiation physics consult	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77371	Srs multisource	Radiation Treatment Delivery
77372	Srs linear based	Radiation Treatment Delivery
77373	Sbrt delivery	Radiation Treatment Delivery
77385	Ntsty modul rad tx dlvr smpl	Radiation Treatment Delivery
77386	Ntsty modul rad tx dlvr cplx	Radiation Treatment Delivery
77399	External radiation dosimetry	Medical Radiation Physics, Dosimetry, Treatment Devices, Special Services
77402	Radiation treatment delivery	Radiation Treatment Delivery
77407	Radiation treatment delivery	Radiation Treatment Delivery
77412	Radiation treatment delivery	Radiation Treatment Delivery
77417	Radiology port images(s)	Radiation Treatment Delivery (Guidance)
77427	Radiation tx management x5	Treatment Management
77431	Radiation therapy management	Treatment Management
77432	Stereotactic radiation trmt	Treatment Management
77435	Sbrt management	Treatment Management
77470	Special radiation treatment	Treatment Management
77499	Radiation therapy management	Treatment Management
77520	Proton trmt simple w/o comp	Radiation Treatment Delivery

HCPCS	HCPCS Description	Category
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)
C1716	Brachytx, non-str, gold-198	Radiation Treatment Delivery (Brachytherapy Materials)
C1717	Brachytx, non-str,hdr ir-192	Radiation Treatment Delivery (Brachytherapy Materials)
C1719	Brachytx, ns, non-hdrir-192	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)

HCPCS	HCPCS Description	Category
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)